California State Board of Pharmacy
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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee Report

Bill Powers, Board President and Chair
Ruth Conroy, PharmD, Board Member
Robert Swart, PharmD, Board Member
Stan Goldenberg, RPh, Board Member

Including Report of the Meeting of March 21, 2007

A summary of the Enforcement Committee and Workgroup on E-Pedigree Meeting held March 21, 2007 is provided in **Attachment A,** near the back of this tab section.

A. Proposal to Develop an Ethics Course for Pharmacists Disciplined by the Board

NO RECOMMENDATION FROM THE COMMITTEE: UPDATE ONLY

At the January 2007 Board Meeting, the board voted to form an exploratory subcommittee to examine the development of an ethics course for pharmacists as a enforcement option as part of discipline. The subcommittee was directed to report back to the board at the October Board Meeting.

Since the January Board Meeting, President Powers appointed Dr. Ravnan and Dr. Swart to this subcommittee; however, t here has been no meeting yet of this group.

B. Update of the Enforcement Committee's Strategic Plan for 2007-08

FOR ACTION:

Amend and approve the committee's strategic plan for 2007-08 by adding two activities to objective 1.5 "institute policy review of 25 emerging enforcement issues by June 30, 2011"; specifically, to add:

4. **Evaluate establishment of an ethics course as an enforcement option.**
5. **Participate in emerging issues at the national level affecting the health of Californians regarding their prescription medicine.**

The committee reviewed its strategic plan for relevance and currency. Two recommendations were made to keep the plan current with all committee activities.

A copy of the committee's strategic plan with the two proposed changes is provided in **Attachment 1**. The amendment proposed is indicated above.

C. Letter of concern to CMS regarding the Federal Deficit Reduction Act's Use of Average Manufacturers' Price as the Reimbursement Base for Medications for Medicaid Patients

FOR INFORMATION:

At the January 31, 2007 Board Meeting, the board voted to submit comments to CMS in response to their proposal to base Medicaid reimbursement upon average manufacturers price. The board's concern was that this policy could lead to pharmacies withdrawing from the program if reimbursement costs are less than their acquisition costs for the medicine. As a result, patient access to pharmacies and medicine, especially in inner city and rural locations may become imperiled.

The letter was written and mailed by the comment deadline. A copy of the letter is provided in **Attachment 2.**

D. Report of the Workgroup on E-Pedigree:

FOR INFORMATION:

A number of important activities have been initiated since the January 2007 Board Meeting.

1. EPCglobal Ratifies Its Pedigree Standard

In early January, EPCglobal released its Ratified Pedigree Standard. A copy of the standard (which is 138 pages) can be downloaded from http://www.epcglobalinc.org/standards

The ratification of this standard is a major milestone!

2. EPCglobal Conducts Hospital Summit

On February 20, EPCglobal held a "summit" in San Diego for California hospitals to initiate awareness of the electronic pedigree requirements and to engage hospitals in what their supply chain partners are doing. Speakers included individuals from hospitals, regulators, and manufacturers (pharmaceuticals, medical devices, biologics, blood products, distributors and vendors). Additional hospital summits are planned by EPCglobal for Boston and Chicago.

As a result of this meeting, the staff is encouraging hospitals to attend the board's quarterly Work Group on Electronic Pedigree meetings. We expect some hospitals will attend the next meeting (June 20) and will encourage the participation of other hospitals.

3. California Board of Pharmacy Review of Pedigree Standard

On March 8, 2007, Board Members Bill Powers and Stan Goldenberg and board staff met with nine EPCglobal representatives to review the EPCglobal Standards and assure the components met California's legal requirements.

This was a lengthy meeting and a summary of the meeting is provided in **Attachment 3**.

The board believes the standard meets California's electronic pedigree requirements. However, additional work and amplification need to be done by industry and by the board. In some cases regulations may be necessary to provide the necessary specification.

4. Workgroup on E-Pedigree Meeting (March 21, 2007)

At this March meeting, the committee heard presentations by the Federal Food and Drug Administration, EPCglobal, AmerisourceBergen and SupplyScape regarding the progress to implement electronic pedigrees into the drug distribution channel for California.

FDA's Status Update: Implementation of the PDMA

The Federal Food and Drug Administration provided a brief update regarding the status of its efforts to implement the PDMA beginning December 1, 2006, to require paper pedigrees for all drugs distributed outside the authorized distribution channel (manufacturer to specific wholesaler to specific pharmacy). A portion of this implementation had been stopped by a federal judge's order in December.

The FDA was enjoined from implementing one section of the PDMA – 21CFR 203.50(a), which specifies the type of information that must be provided on the pedigree. The FDA is appealing this decision, but noted that the preliminary injunction did not affect the requirement that pedigrees must start once drugs are sold outside the last authorized distributor of record.

The FDA also updated the committee regarding the status of stability studies it had initiated regarding use of electronic pedigrees on certain drug products. The results of these studies have not yet been analyzed or compiled into a report. The results will perhaps be released later this year.

However, the FDA staff did commend the board for its ongoing efforts to institute electronic pedigree requirements for California as an important step in securing the drug distribution channel.

EPCglobal Update:

Bob Celeste of EPCglobal provided a presentation of where EPCglobal is with respect to its standards setting project for electronic pedigrees (**Attachment 4**).

In early January 2007, EPCglobal finalized the standard for electronic messaging. This is a major milestone for the implementation of electronic pedigree requirements. The new pedigree standard will support item level serialization, electronic signatures, RFID using non-line of sight identification of pallets, cases or items, and inference.

Mr. Celeste stated that there are now nearly 80 business partners participating in weekly conference calls with EPCglobal on implementation issues involving electronic pedigrees.

A brief summary of EPCglobal's progress (as reported at the March meeting) in seven areas is:

- Pedigree management use cases: objective: define all supply chain use cases, processes and information needs for use in creating pedigree messaging standards.
  Status: complete
- Pedigree messaging standards: objective: define a standard format for the pedigree-messaging standard that meets all federal and state requirements.
  Status: complete
- Item level tagging: objective: define requirements for tagging pharmaceuticals at the item level; this includes requirements for manufacturing lines, distribution environments, transportation and retail environments.
  Status: requirements complete. A high frequency technical work was formed to define the standard. High frequency and ultra high frequency pilots are underway to provide uniform air interface protocol at the item level. The high frequency standard is expected to completed in the 3rd quarter of 2007
- Serialization: objective: define requirements to be encoded on the electronic tag.
  Status: requirements completed. Two identifiers were identified for use (global trade item number (GTIN) and serialized shipping container number (SSCC)). The newly formed serialization group will address all remaining issues.
- Authenticating and Decommissioning: objective: define requirements for authenticating and decommissioning tags for optimizing tag utility and consumer privacy.

Status: work to begin in March 2007, timeline is 6 months. The DEA is very interested in this. The solutions will span a mix of hardware, software and process responses, and perhaps cross industry.

- Track and trace: objective: define supply chain use cases, processes and information needs for sharing EPC-related data for forward and reverse logistics.
  Status: forward and reverse logistics processes and data exchanges completed, common vocabularies and location identifiers drafted, additional use cases to be addressed for 3rd party logistics and repackagers, product recall, data sharing strategy and guidelines, and pedigree on demand concepts are being developed.
- Tag Data Standards: objective: define additional memory requirements for tags (i.e., lot number expiration date)
  Status: Work underway; defining common data structure that can be used by all industries.

Mr. Celeste stated that the track and trace standard is expected to be complete in the third quarter of 2007.

AmerisourceBergen

Heather Zenk, AmerisourceBergen Corporation, provided an update of the pilot it is initiating with IBM on electronic pedigrees at its facility in Sacramento. A full presentation on this pilot was provided at the last Enforcement Committee Meeting, and by IBM at the January Board Meeting. A copy of this presentation is provided in **Attachment 5.**

AmerisourceBergen initiated this project in the area of track and trace as an alternative to document-based pedigree tracking that would create massive data as drug products pass from one owner to the next through the distribution channel. At each successive step in the distribution channel, more data would be added to the database for each drug product, resulting in massive redundant data repositories, especially for those near the end of the distribution channel. There is little other use that a company will gain from such repositories, except for compliance with requirements.

Instead ABC is testing a "track and trace" model using technology from IBM. This system passes only a minimal amount of data as the product moves through the distribution channel, but that at any point, full data describing all items and all ownership can be quickly accessed and obtained by legitimate users. The system can also be accessed to obtain real time receiving and shipping information and for better management of inventory.

The ABC pilot will use ultra high frequency, 2-D bar codes and new high frequency tags on the drug products tested. Inference will be one component evaluated as products are shipped from manufacturer to wholesaler. Inference

also will be evaluated on mixed totes of products from wholesalers to pharmacies. Board staff indicated at the Enforcement Meeting that these practices will be carefully reviewed for compliance with California requirements as the data is collected during the pilot.

The project is expected to begin in May 2007.

SupplyScape

Lucy Deus, SupplyScape, provided a PowerPoint presentation on SupplyScape's experience with electronic pedigree adoption. A copy of this presentation is provided in **Attachment 6.**

Ms. Deus emphasized that a company can leverage pedigree data into other business operations, but that the benefits of electronic pedigree adoption are not automatic. Companies need to look at their business operations and recognize how data generated from electronic tracking can benefit their operations. There are substantial opportunities for companies to gain a return on their investment in adopting pedigrees. For example, by integrating pedigree software into "critical touch" points in business practices this can aid companies in other operations such as in gaining physical and financial information regarding inventory, returns, reconciliation, shelf-life management and facilitated identification of lots subject to recall.

She stated that the memory requirements for storage of pedigree data are quite small based on the experience of one retailer, who had over 50 million items reported during the course of one year, but only 700 MB of storage was needed, which on new computers for about 100 times this amount of memory, is about $50.

4. Meeting Summary

A summary of the December 12, 2006 Enforcement Committee and Workgroup on E-Pedigree is provided as **Attachment A**.

5. Report on Enforcement Actions

A report of enforcement actions taken since July 1, 2006 is provided as **Attachment B**.

Attachment 1

Strategic Plan Revision for 2007-08

GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1 Measure:	Achieve 100 percent closure or referral on all cases within 6 months by June 30, 2011: Percentage of cases closed or referred within 6 months
Tasks:	1. Mediate all consumer complaints within 90 days. 2. Investigate all other cases within 120 days. 3. Close (e.g. issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.
Objective 1.2 Measure:	Manage enforcement activities for achievement of performance expectations Percentage compliance with program requirements
Tasks:	1. Administer the Pharmacists Recovery Program. 2. Administer the probation monitoring program. 3. Issue citations and fines within 30 days 4. Issue letters of admonition within 30 days 5. Obtain immediate public protection sanctions for egregious violations. 6. Pursue petitions to revoke probation within 90 days for noncompliance with probationary conditions.
Objective 1.3 Measure:	Achieve 100 percent closure on all administrative cases within one year by June 30, 2011. Percentage closure of administrative cases within 1 year
Objective 1.4 Measure:	Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2011. Percentage of licensed facilities inspected once every 3 years
Tasks:	1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public. 2. Inspect sterile compounding pharmacies annually before renewal or before initial licensure. 3. Initiate investigations based upon violations discovered during routine inspections.

Objective 1.5 Measure:	Initiate policy review of 25 emerging enforcement issues by June 30, 2011 The number of issues
Tasks:	1. Monitor the implementation of e-pedigree on all prescription medications sold in California 2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products 3. Monitor the efforts of the DEA and DHHS to implement electronic prescribing for controlled substances. 4. Evaluate establishment of an ethics course as an enforcement option. 5. Participate in emerging issues of the national level affecting the health of Californians.

Attachment 2

Board Letter to the CMS Regarding Decreased Patient Access to Pharmacies if AMP is Used as the Reimbursement Base for Medicaid Patients

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

February 16, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8015
Baltimore, MD 21244-8015

RE: File Code CMS-2238-P

Dear Sir or Madam:

The California State Board of Pharmacy (Board) appreciates this opportunity to submit comments on the proposed rulemaking in 42 CFR Part 447 (File Code CMS-2238-P), the purpose of which is to implement provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid program. While the Board is pleased that an attempt is being made to clarify this difficult subject area, and recognizes the constraints and mandates placed on CMS by the provisions of the DRA, the Board is concerned that the proposed rules, as written, may result in significant barriers to access necessary medication(s) by California residents who are recipients of Medicaid, particularly in rural and inner city locations.

The primary mandate of the Board is protection of the health and safety of the public in California. In the realm of drug distribution and treatment, this includes helping to ensure a safe, reliable, drug supply, and timely access to medications necessary for treatment.

When such access is impaired, particularly in vulnerable populations such as is often the case for recipients of Medicaid, public health and safety are also impacted. Furthermore, where the concern is overall health system cost savings, any such impairment of access to drugs, particularly among vulnerable populations, may lead to greater overall costs due to increased Emergency Room visits, hospitalizations, or aggravation of preexisting conditions due to an interruption of drug therapy.

We are concerned that the proposed rules may have this detrimental effect on access. We have heard from numerous stakeholders in the pharmaceutical industry, especially but not exclusively community pharmacies both large and small, that the proposed rules would make it economically infeasible for them to continue participating in Medicaid and/or providing drugs to Medicaid recipients in California. They have concluded that

the proposed rules would result in reimbursement and dispensing rates significantly below the lowest prices at which they can purchase the drugs to be dispensed.

Stakeholders in the industry will certainly express to CMS their specific concerns about the text of the proposed rulemaking more comprehensively than the Board, but as articulated to the Board, the difficulties with the current rules include: despite an acknowledgment of flaws in AMP data as a predictor of actual costs-to-dispense, CMS intends to rely on (and to publicly release) that data before resolving its uncertainties and unreliability; the given definition of AMP does not accurately reflect actual acquisition costs by pharmacies; the proposed rules for generics reimbursement will significantly undercount the actual costs of purchasing such drugs, by up to an average of 36 percent;[1] and without any direction to states to increase dispensing fees (particularly for generics), the average dispensing fee payment of $4.50 is significantly below the actual costs-of-dispensing for pharmacies nationwide which has been cited to be between $10.00 and $12.00.[2] The overall message that has been delivered is that the new rules may very well result in a reduction or even elimination of the retail sites that are willing or fiscally able to dispense drugs to Medicaid recipients.

In his May 12, 2006 letter to Secretary Leavitt, Senator Charles Grassley also expressed a similar concern that states must be encouraged or required to reconsider their dispensing fees paid to pharmacies to compensate for presumably lowered drug costs under the new AMP-based calculation protocol. As Senator Grassley said:

> I expect states will very soon begin shifting to a pharmacy payment methodology based on the newly published interim AMP data. CMS should make clear to states that they should reconsider their dispensing fees paid to pharmacies under Medicaid particularly for generic drugs. *States may have been working under an assumption borne out in numerous reports of the Office of the Inspector General that pharmacies were being reimbursed well beyond the acquisition cost of the drugs and so dispensing fees were set at levels below the actual cost of the dispensing of a drug. States should carefully consider data regarding the cost of dispensing in determining dispensing fees at the same time they change their reimbursements for acquisition cost to be more consistent with the actual cost of acquisition.*

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[1] See *Medicaid Outpatient Drugs: Estimated 2007 Federal Upper Limits for Reimbursement Compared with Retail Pharmacy Acquisition Costs*, GAO Report No. GAO-07-239R (December 22, 2006).

[2] See *National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies*, prepared by Grant Thornton LLP for The Coalition for Community Pharmacy Action (January 2007).

The Board agrees that in order to ensure appropriate access to prescription drugs for those residents of California who are recipients of Medicaid, the final result of this rulemaking must be that a combination of reimbursement and dispensing fees paid equals or exceeds the actual cost(s) of drug dispensing. Otherwise, access will be rapidly diminished.

Thank you for this opportunity to provide comments.

Sincerely,

William Powers

WILLIAM POWERS
Board President

Attachment 3

Meeting Summary of the March 8, 2007 EPCglobal Meeting with Board Representatives

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Meeting Summary
March 8, 2007

California Board of Pharmacy Review of EPCglobal's Electronic Pedigree Standard

1625 N. Market Boulevard
Sacramento, CA 95834
9 a.m. – 3 p.m.

Present: Bill Powers, Board President
Stan Goldenberg, RPh, Board Member
Virginia Herold, Executive Officer
Judi Nurse, Supervising Inspector
Joshua Room, Deputy Attorney General,

From EPCglobal:
Ron Bone, CoChair, EPCglobal Healthcare & Life Sciences Industry Action Group
Mike Rose, CoChair, EPCglobal Healthcare & Life Sciences Industry Action Group
Dirk Rodgers, CoChair, Pedigree Working Group
Eric Douglass, EPCglobal Retail Representative
Grant Hodgkins, CoChair, EPCglobal Adoption Group
John Howells, CoChair, EPCglobal Track & Trace Group
Bryan Bond, substituting for Public Policy, Adoption Member
Tom Pizutto, Industry Member
Robert Celeste, Director, Healthcare, EPCglobal North America

The meeting started with a detailed review of the pedigree standard, and the information that is appended to the pedigree at each step in transactions involving a change in ownership as a drug moves from a manufacturer to a pharmacy. The discussion included the electronic pedigree format, the initial pedigree components and how shippers and receivers annotate to the pedigree. Mixed into this discussion were descriptions about how various segments of the distribution channel would append the pedigree. A detailed list of discussion points used to frame the meeting is provided as Attachment A.

Specific Discussion Items:

1. The California pedigree law requires that a single pedigree include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another NDC number.

   A question was raised about how to handle bulk repackaging; for instance, where tablets from several/numerous bulk containers, cases, lots, etc. are mixed together and repackaged, separating tablets from their original containers/lots (and original pedigrees).

   One suggestion was to modify business practices so that all such "source" tablets are from the same manufacturer lot/shipment.

2. The California pedigree law requires that the pedigree track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the drug.

   A question was raised about how to handle "unit dose" packaging (e.g., individual-dose packaging used in hospitals or physician's offices), which may present additional challenges for attachment of data elements sufficient to generate a pedigree serialized to this level.

3. The California pedigree law requires that the pedigree include, among other things, a certification as to accuracy of the pedigree from the source of the dangerous drug, and identifying information/signatures from responsible parties at both the delivering and receiving entities, verifying shipment. The EPCglobal standard incorporates the requirement that both the sender and receiver enter an electronic signature to verify shipment and receipt.

   A question was raised about the timing of the signature and verification of shipment upon receipt, i.e., whether that signature (and/or the verification of the drugs received to the pedigree) requires that the entire shipment be verified down to the serialized bottle or other immediate container before delivery is accepted, or if the recipient may "infer" accuracy of the shipment based on verification at the lot, case, pallet, or other aggregate level, subject to subsequent verification of the shipment down to the serialization level.

4. The California pedigree law does not presently allow for or define circumstances under which a pedigree may be "voided" or the RFID tags (if used) "turned off"/decommissioned.

   Questions were raised about what to do, for instance, when drugs subject to a pedigree are destroyed (or returned for destruction), or if there is a material inaccuracy in the pedigree itself.

5. The California pedigree law requires that every change in ownership be recorded on the pedigree. The pedigree is part of the records of acquisition and disposition of a drug, so must travel with the drug even where no change in ownership has taken place.
   A question was raised about how to handle "drop shipments" directly from manufacturers to pharmacies, where the pharmacy places the order directly with the manufacturer, and the drug(s) are shipped (at least some of the time on an emergency or expedited timeline)

directly to the pharmacy, but for business/billing reasons the economics of the transaction are handled through a wholesaler (i.e., the wholesaler bills the pharmacy, and pays the manufacturer). In these cases, the wholesaler never takes possession of the drugs, which are delivered directly from manufacturer to pharmacy.

6. The California pedigree law requires that every change in ownership be recorded on the pedigree; it specifically requires that any return of a drug to a wholesaler or manufacturer be documented on the same/single pedigree.

   A question was raised about whether it would be possible (for marketing/business reasons) to "restart" the pedigree: when a returned drug has been thoroughly tested/authenticated by the manufacturer, and is shipped back out under circumstances identical to its initial shipment, could the manufacturer create a new pedigree (i.e., be "exempt" from the single pedigree requirement)?

ATTACHMENT A

California Board of Pharmacy
Review of EPCglobal Pedigree Messaging Standard

1. **Electronic Pedigree Format**
The basic components of a pedigree are shown. The components in an actual pedigree depend on the specific business situation in which it is used (e.g., pedigree initiated by manufacturer, pedigree initiated by wholesaler, pedigree for repackaged item, etc.).

2. **Initial Pedigree Components**
The diagrams illustrate the different forms the innermost content of the pedigree may take before the content is nested in the first shippedPedigree layer. These components do not represent complete shipped and received pedigrees. In order to represent a complete pedigree, the innermost content is embedded in a shippedPedigree and digitally signed with a Signature element.
   a. **Innermost content for a manufacturer pedigree** (initiated by manufacturer, before a wholesale distribution)
   b. **Innermost content for a wholesaler pedigree** (initiated by first wholesaler, includes transaction information for first wholesale distribution)
   c. **Innermost content for a wholesaler pedigree with attachment** (initiated by wholesaler, includes ASN data as attachment to facilitate manual authentication by downstream trading partners)
   d. **Innermost content for a wholesaler pedigree with scanned source pedigree** (initiated by wholesaler, includes previous pedigree which may reflect one or more previous distributions)
   e. **Innermost content for a repacker pedigree** (initiated by repacker, repacked item contains two source pedigrees)
   f. **Innermost content for a kit pedigree where the kit has an assigned NDC** (initiated by kit manufacturer, kit contains two pedigrees)

3. **Shipped and Received Pedigree Components**
The diagrams illustrate the different forms a complete pedigree may take when pedigrees are exchanged between trading partners.
   a. **Signed manufacturer pedigree** (initiated by manufacturer, after the wholesale distribution, signed by both manufacturer and wholesaler)
   b. **Signed wholesaler pedigree** (initiated by wholesaler, after the wholesale distribution, signed by both wholesaler and retailer DC)
   c. **Signed repacker pedigree** (initiated by repacker, after wholesale distribution, signed by both repacker and wholesaler recipient)
   d. **Signed kit pedigree** (kit has NDC, initiated by kit manufacturer, after wholesale distribution, signed by both kit manufacturer and wholesaler recipient)
   e. **Pedigree with two signed transactions** (initiated by manufacturer, received and signed inbound by wholesaler recipient, signed outbound by wholesaler upon shipment to pharmacy, received and signed inbound by pharmacy recipient)

f. **Pedigree without inbound receipt signature** (initiated by manufacturer, received but not signed inbound by wholesaler recipient, signed outbound by wholesaler upon shipment to pharmacy)
g. **Pedigree without inbound receipt information or signature** (initiated by manufacturer, signed outbound by wholesaler upon shipment to pharmacy)
h. **Pedigree with partial receipt** (initiated by manufacturer, updated with partial receipt information and signed inbound by wholesaler recipient for first receipt, and then generation of another received pedigree with remaining receipt information and signature for second receipt)
i. **Pedigree with return transaction** (initiated by manufacturer, received and signed inbound by wholesaler, return transaction applied by wholesaler for manufacturer return and signed outbound, received and signed inbound by manufacturer)
j. **Pedigree with return transaction applied by wholesaler on behalf of pharmacy** (initiated by wholesaler, signed outbound by wholesaler for shipment to pharmacy, return transaction applied by wholesaler for pharmacy return, signed outbound by wholesaler for subsequent sale)

4. Non-Normative Usage Guidelines for Creating and Appending Information to Pedigrees

This section explains how to use the Pedigree element and its sub elements to create pedigrees and append transactional and signature information to them. All content in this section is non-normative.

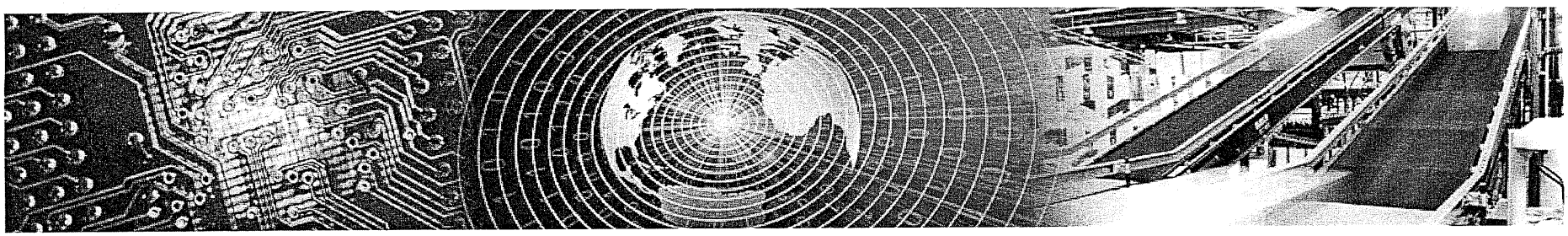
a. **Pedigree Flow Initiated by Manufacturer** (The pedigree flow is described for a sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree.)
b. **Pedigree Flow Initiated by Wholesaler** (The pedigree flow is described for a sale from a wholesaler to a retail pharmacy DC, when no pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.)
c. **Pedigree Flow Initiated by Wholesaler from Paper Pedigree** (The pedigree flow is described for a sale from a wholesaler to a retail pharmacy DC, when the prior pedigree was in paper form and the receiving information was applied to the paper pedigree, and the wholesaler converts the pedigree to electronic form prior to the sale to the retail pharmacy DC.)
d. **Pedigree Flow Initiated by Repacker** (The pedigree flow is described for a sale from a repacker to a wholesaler, where the repacker initiates the pedigree for a repackaged item. A repack pedigree may or may not contain the pedigrees for the source products used to create the repack products, depending on the regulatory requirements of a given pedigree law. The usage guideline describes how to construct the pedigree for both scenarios, when the source pedigrees are required and when they are not required. The usage guideline also describes how to include the source pedigree when the source pedigree is an electronic pedigree created or received, or

a pedigree received in an alternate form, such as a scanned paper pedigree.)

e. **Pedigree Flow for a Kit** (A kit is a packaged product that can contain one more prescription drugs. Kits containing prescription drugs may or may not have an NDC assigned to the kit itself. This usage guideline describes the process for creating a kit that has an assigned NDC. If the kit does not have an assigned NDC, one of two options can be utilized:)
f. **Partial Receipt of Products against Pedigree** (The partial receipt of product against pedigree is described for a sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. The wholesaler receives the products in two partial shipments and updates each partial receipt against the original pedigree, resulting in a new received pedigree for each partial receipt.)
g. **Pedigree Receipt without Applying Receiving Signature** (The flow for the receipt of a pedigree without signing the pedigree on inbound receipt is described. The pedigree is subsequently signed on the next outbound transaction.)
h. **Pedigree Flow for Pedigree with Two Transactions** (The pedigree flow is described for a sale from a manufacturer to a wholesaler and then the wholesaler to a pharmacy.)
i. **Pedigree Flow for Pedigree with Return Transaction** (The pedigree flow is described for a sale from a manufacturer to a wholesaler and then with a return from the wholesaler back to the manufacturer. The party making the return applies the return transaction to the pedigree.)
j. **Pedigree Flow for Wholesaler Applied Return Transaction to Pedigree** (The pedigree flow is described for a sale from a wholesaler to a pharmacy, and then a return from the pharmacy back to the wholesaler with the wholesaler updating the pedigree with the return transaction.)
k. **Pedigree Flow for a Manufacturer-initiated Drop Ship** (The pedigree flow is described for a drop ship transaction brokered by wholesaler, where pharmacy purchases the product from the wholesaler, but the manufacturer ships the product directly to the pharmacy. In this scenario, the manufacturer initiates the start of the drop ship pedigree documenting the sales transaction from the manufacturer to the wholesaler with the shipping information indicating the direct shipment to the pharmacy. The wholesaler adds only the second part of the drop ship transaction to the pedigree documenting the sales transaction from the wholesaler to the pharmacy.)
l. **Pedigree Flow for a Wholesaler-initiated Drop Ship** (The pedigree flow is described for a drop ship transaction brokered by wholesaler, where pharmacy purchases the product from the wholesaler, but the manufacturer ships the product directly to the pharmacy. In this scenario, the manufacturer does not provide the wholesaler with a pedigree and the wholesaler documents both parts of the drop ship transaction on the pedigree (assuming the wholesaler has access to this information).)

Attachment 4

EPCglobal's Presentation on the State of Pedigree and EPC/RFID Standards
March 21, 2007



EPCglobal HLS Update

State of Pedigree and EPC/RFID Standards

California Board of Pharmacy

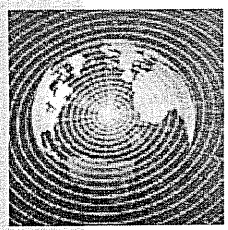
Enforcement Committee

March 21, 2007

Bob Celeste

Director, Healthcare, EPCglobal North America

GS1 EPCglobal



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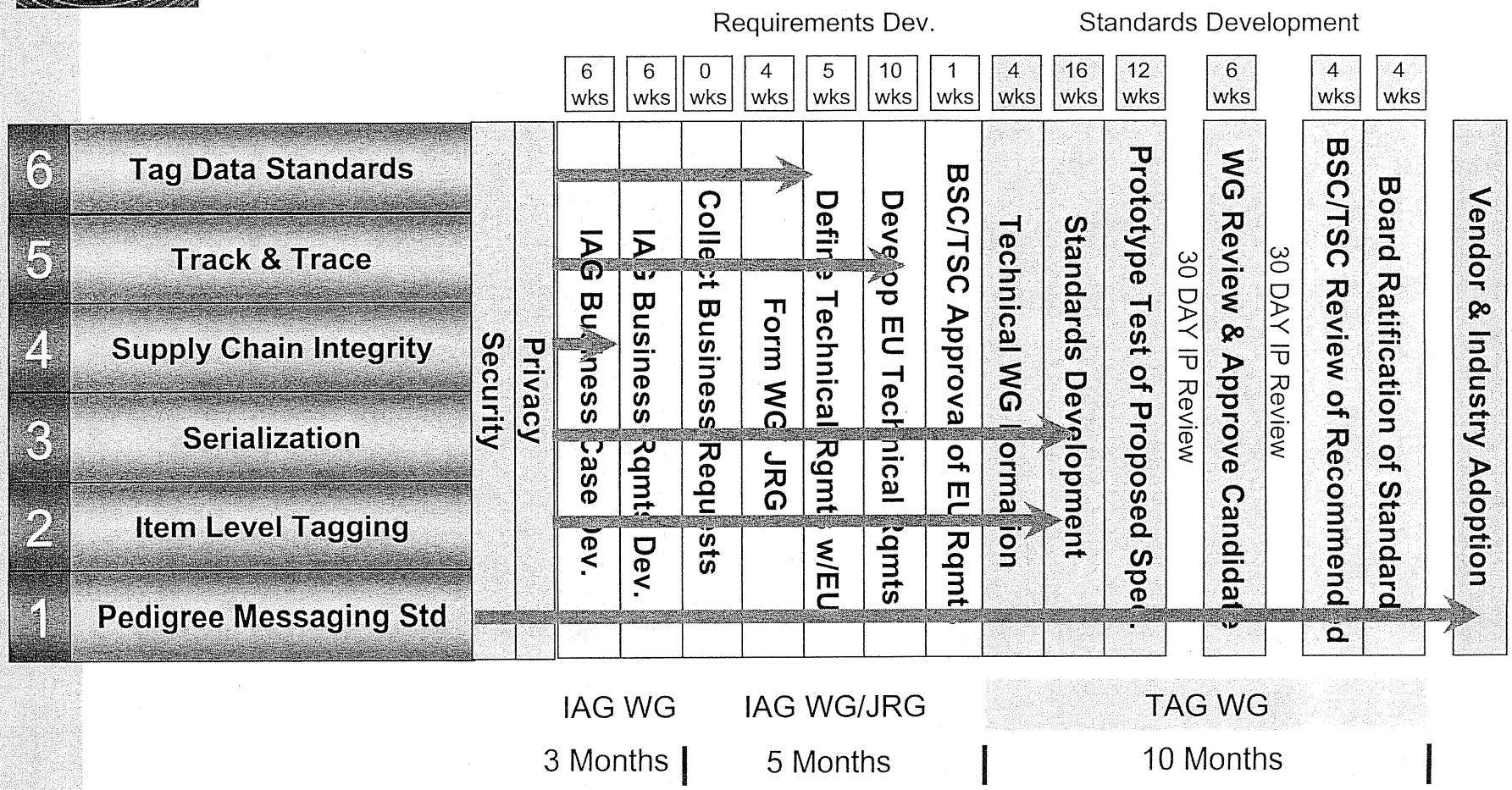
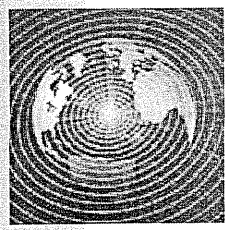
  - Business Scenarios
  - Pedigree Software Certification
- Pedigree Review Follow-Up Items

Standards Update

Current Status



GS1 EPCglobal



Standards Update

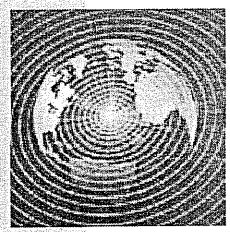
6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define a standard format for a Pedigree Messaging standard that will meet all current Federal and State Pedigree requirements.

Status:

- All Standards work complete.
- **Ratified standard – 01/2007**
- Certification Program underway

GS1 EPCglobal



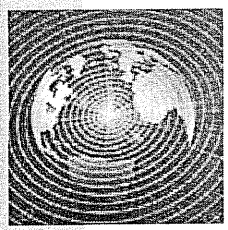
Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements for tagging pharmaceuticals at the item level. Include requirements for manufacturing lines, distribution environments, transportation and Retail environment.

Status:

- Requirements complete. Resulted in a High Frequency technical working group to define the standard.
- HF & UHF initiatives underway to provide uniform air interface protocol at item level.
- HF Standard expected '07.



Standards Update

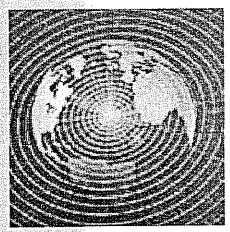
6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	**Serialization**
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements for the EPC identifier to be encoded on an RFID tag.

Status:

- Requirements complete. Identified 2 GS1 identifiers [Global Trade Item Number (GTIN) and Serialized Shipping Container Number (SSCC)] to be used.
- Collaborating with GS1/HUG via the "Global Healthcare Initiative" -- starting with Serialization.
  - Joint HUG/HLS Work Team

GS1 EPCglobal



Standards Update

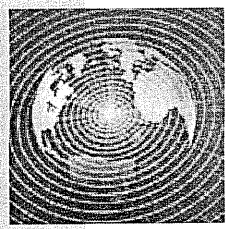
6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define requirements and/or guidelines for authenticating and decommissioning tags consistent with optimizing tag utility and consumer/patient privacy.

Status:

- Work Group has been approved and will start in March 2007
- US Drug Enforcement Agency interest in this capability is extremely high
- Solutions expected to span a mix of hardware, software and process responses
- Potential for this work to expand cross-industry

GS1 EPCglobal



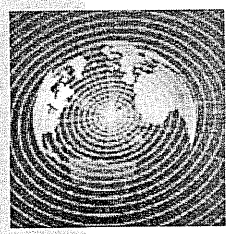
Standards Update

6	Tag Data Standard
5	Track & Trace
4	Supply Chain Integrity
3	Serialization
2	Item Level Tagging
1	Pedigree Messaging Std

Define supply chain use cases, processes and information needs for sharing EPC related data for forward and reverse logistics.

Status:

- Forward & Reverse Logistics (Returns) processes and data exchanges completed
- Common vocabularies and location identifiers drafted
- Additional use cases to be addressed:
  - 3rd Party Logistics Providers & Repackers
  - Product Recall
- Data Sharing Strategy & Guidelines are currently being addressed
- Pedigree-on-Demand concepts being Investigated
- Integrate with GS1 Traceability efforts

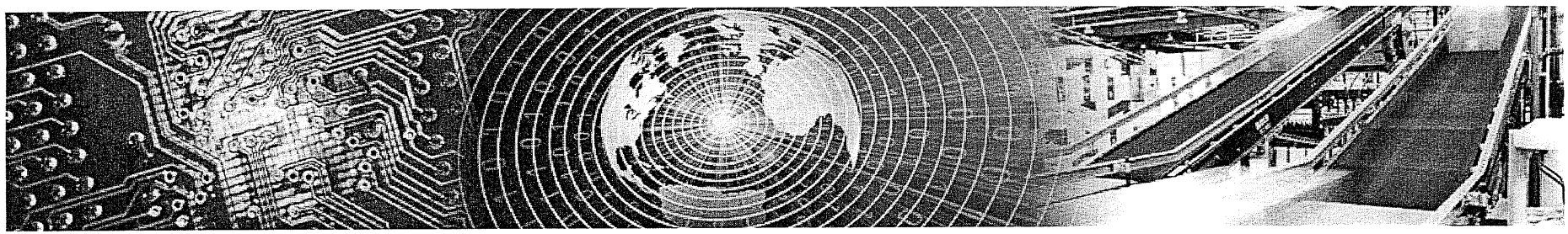


Standards Update

6	**Tag Data Standards**
5	**Track & Trace**
4	**Supply Chain Integrity**
3	**Serialization**
2	**Item Level Tagging**
1	**Pedigree Messaging Std**

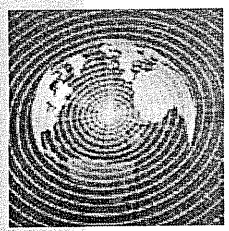
Define additional user memory requirements for tags (ie. Lot Number, Expiration Date).

Status: Work underway. Defining common data structure that can be used by all industries.



Pedigree Overview

GS1 EPCglobal



Pedigree Review
Agenda

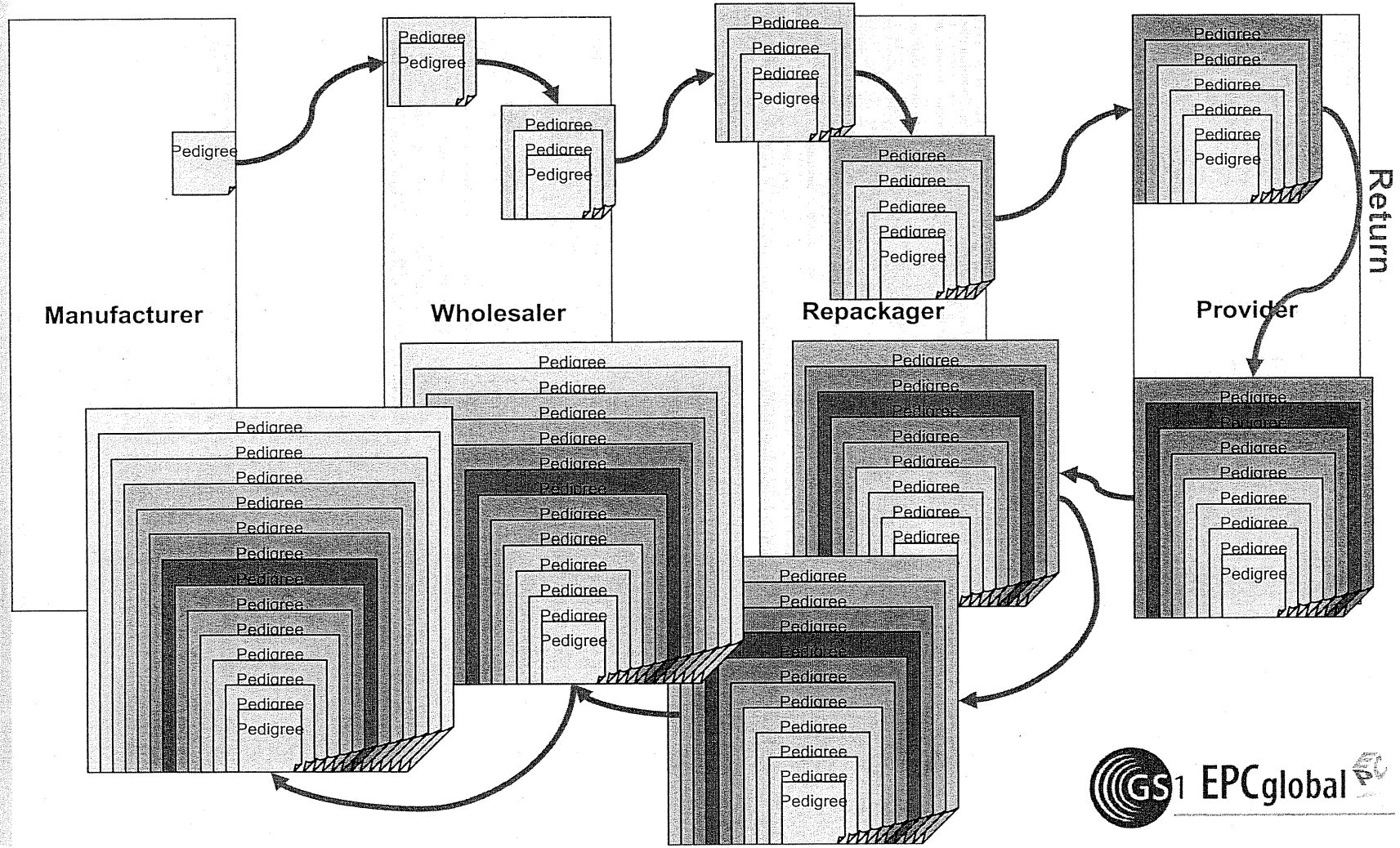
- Structure of the Pedigree Standard
  - Pedigree Format
  - Pedigrees for different Business Situations
- Implementation Guidelines Review
- Sample Pedigree data for applicable Scenarios
- Pedigree Software Certification Process

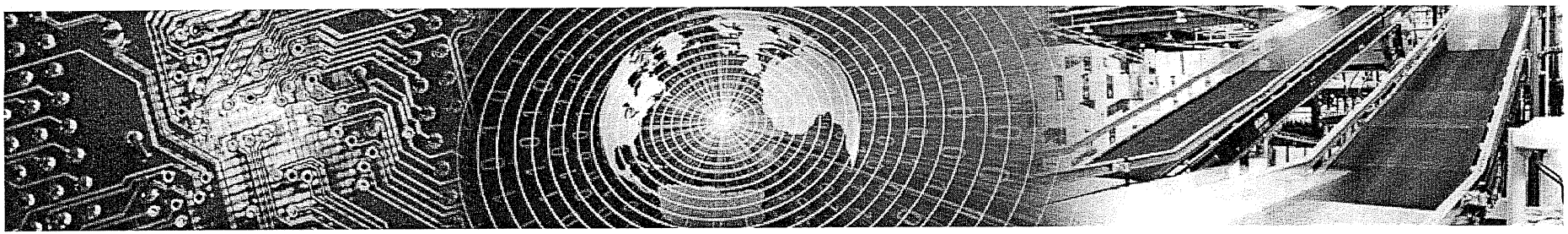
Review of Pedigree Standard
Features Supported

Feature	Required?	Support?
Item level serialization - Unique identification of each and every bottle of medication	No	Yes
Electronic Signatures - Ensures identity of Pedigree issuing company	Yes	Yes
RFID - Non Line of sight identification of Pallets, Cases or Items	No	Yes
Inference - Upon visual inspection, assuming content of containers (Pallets, Cases, Totes) based on Pedigree or Advanced Ship Notice (ASN)	No	Yes
Manufacturer initiated Pedigree - Manufacturer sends first pedigree to next participant in supply chain (as opposed to the first distributor)	No	Yes

Document Based Pedigree

Passing the Pedigree through the supply chain

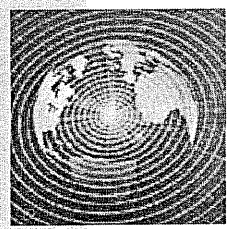




Electronic Pedigree Format

The basic components of a pedigree are shown in the following figure. The components in an actual pedigree depend on the specific business situation in which it is used (e.g., pedigree initiated by manufacturer, pedigree initiated by wholesaler, pedigree for repackaged item, etc.).

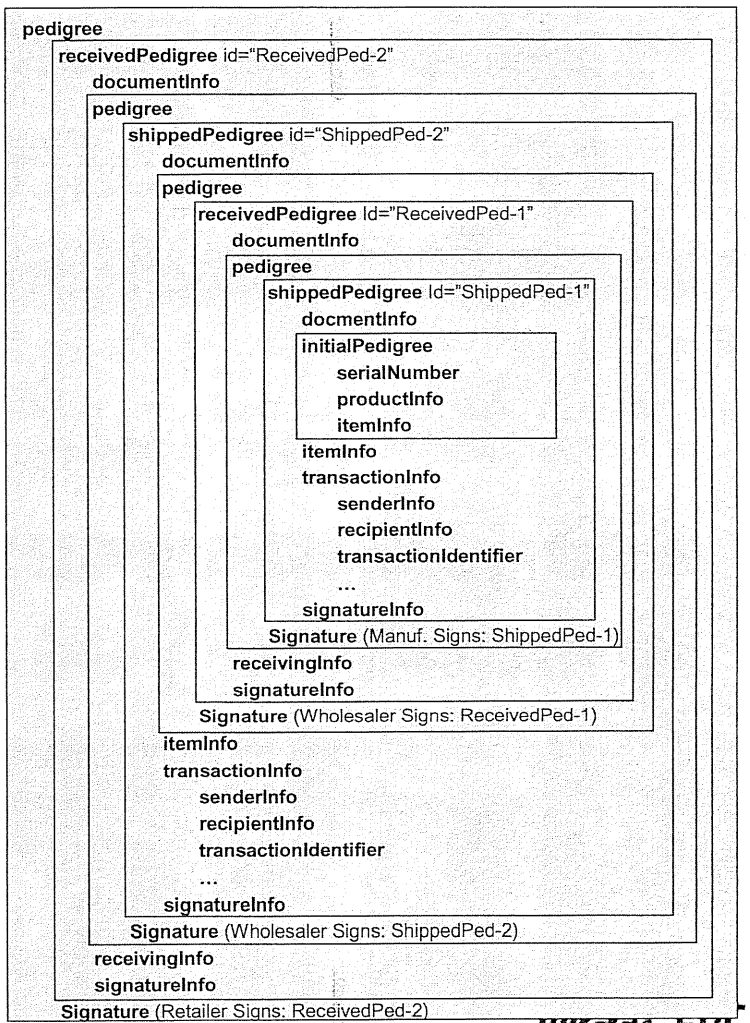
GS1 EPCglobal



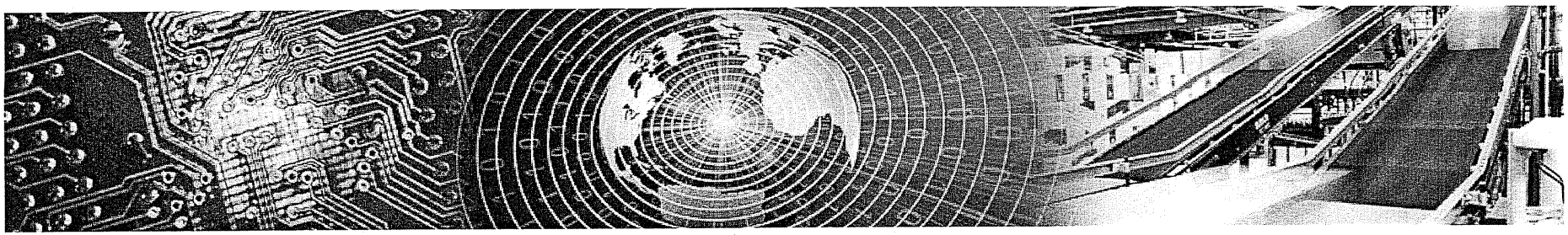
Electronic Pedigree Format

Electronic Pedigree Format

The basic components of a pedigree are shown in the following figure. The components in an actual pedigree depend on the specific business situation in which it is used (e.g., pedigree initiated by manufacturer, pedigree initiated by wholesaler, pedigree for repackaged item, etc.).



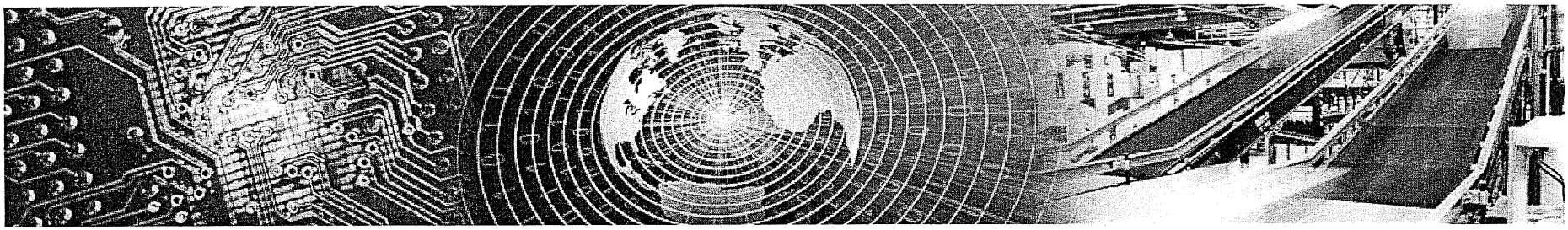
GS1 EPCglobal



Forms for Pedigree Components for Specific Business Situations (non-normative)

A pedigree and data components within the pedigree may take one of several forms depending on the context of how the pedigree was created or received (e.g., manufacturer initiated pedigree, wholesaler initiated pedigree, pedigree for repackaged item, conversion of alternate pedigree, etc.). The table below provides a non exhaustive list of use cases and the corresponding form a pedigree component may take for each of these use cases.

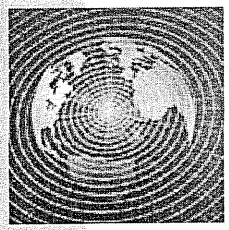
GS1 EPCglobal



Initial Pedigree Components

The following diagrams illustrate the different forms the innermost content of the pedigree may take before the content is nested in the first shippedPedigree layer. These components do not represent complete shipped and received pedigrees. In order to represent a complete pedigree, the innermost content is embedded in a shippedPedigree and digitally signed with a Signature element.

GS1 EPCglobal

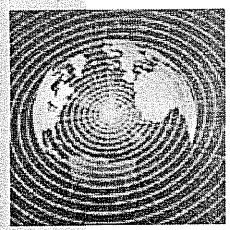


Initial Pedigree Components

Innermost content for a manufacturer pedigree

(initiated by manufacturer, before a wholesale distribution)

initialPedigree
- **serialNumber**
- **productInfo**
  - **drugName**
  - **manufacturer**
  - **…**
- **itemInfo**
  - **lot**
  - **quantity**

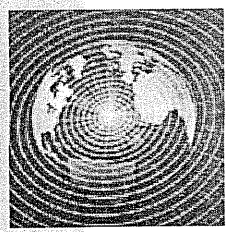


Initial Pedigree Components

Innermost content for a repacker pedigree

(initiated by repacker, repacked item contains two source pedigrees)

repackagedPedigree
- **previousProducts**
  - **serialNumber**
  - **previousProductInfo**
  - **itemInfo**
  - **contactInfo**
- **previousProducts**
  - **serialNumber**
  - **previousProductInfo**
  - **itemInfo**
  - **contactInfo**
- **previousPedigrees**
  - **pedigree**
    - **...**
- **previousPedigrees**
  - **pedigree**
    - **...**
- **productInfo**
  - **drugName**
  - **manufacturer**
  - **...**
- **itemInfo**
  - **lot**
  - **quantity**

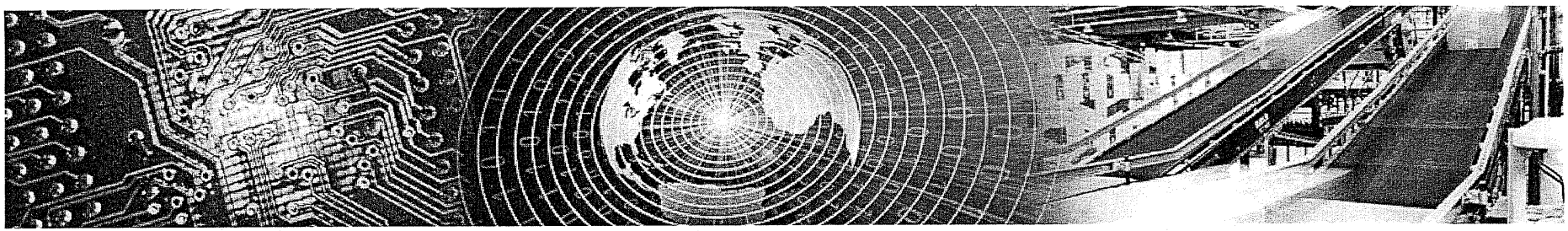


Initial Pedigree Components

Innermost content for a kit pedigree where the kit has an assigned NDC

(initiated by kit manufacturer, kit contains two pedigrees)

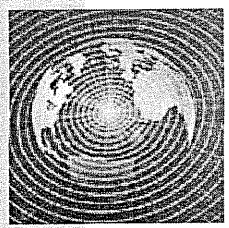
repackagedPedigree
- **previousProducts**
  - **serialNumber**
  - **previousProductInfo**
  - **itemInfo**
  - **contactInfo**
- **previousProducts**
  - **serialNumber**
  - **previousProductInfo**
  - **itemInfo**
  - **contactInfo**
- **previousPedigrees**
  - **pedigree**
    - **...**
- **previousPedigrees**
  - **pedigree**
    - **...**
- **productInfo**
  - **drugName**
  - **manufacturer**
  - **...**
- **itemInfo**
  - **lot**
  - **quantity**



Shipped and Received Pedigree Components

The following diagrams illustrate the different forms a complete pedigree may take when pedigrees are exchanged between trading partners.

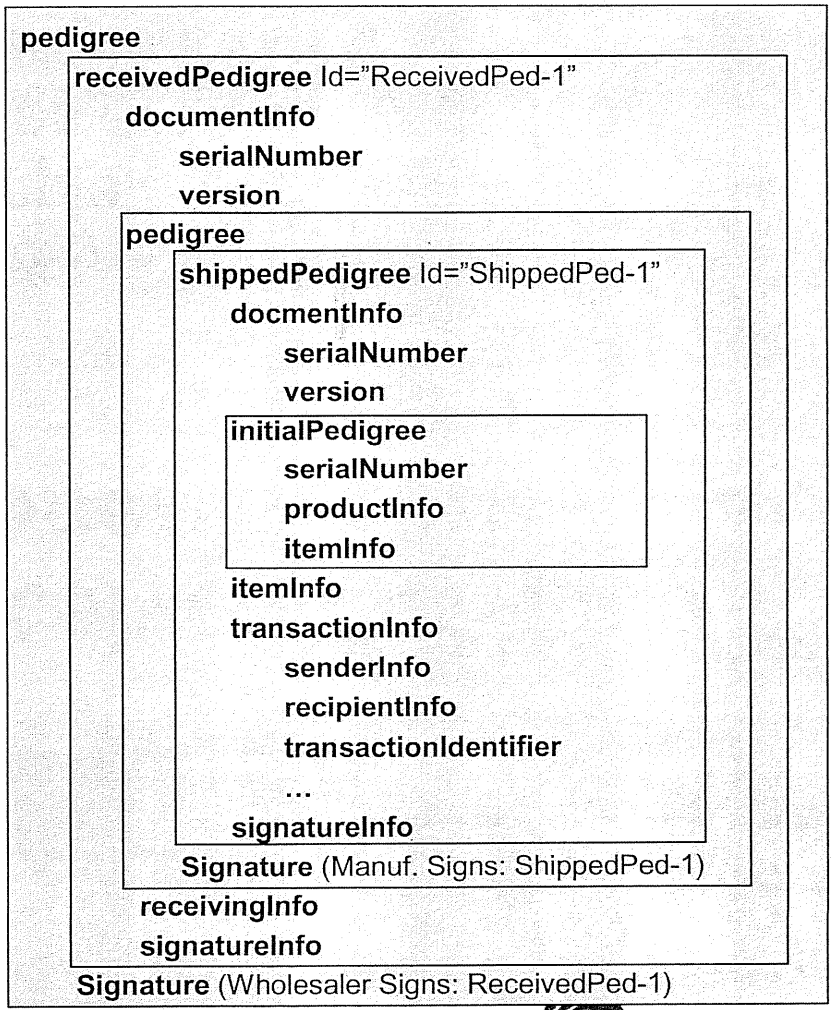
GS1 EPCglobal



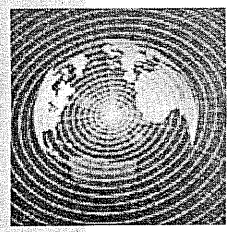
Shipped and Received Pedigree Components

Signed manufacturer pedigree

(initiated by manufacturer, after the wholesale distribution, signed by both manufacturer and wholesaler)



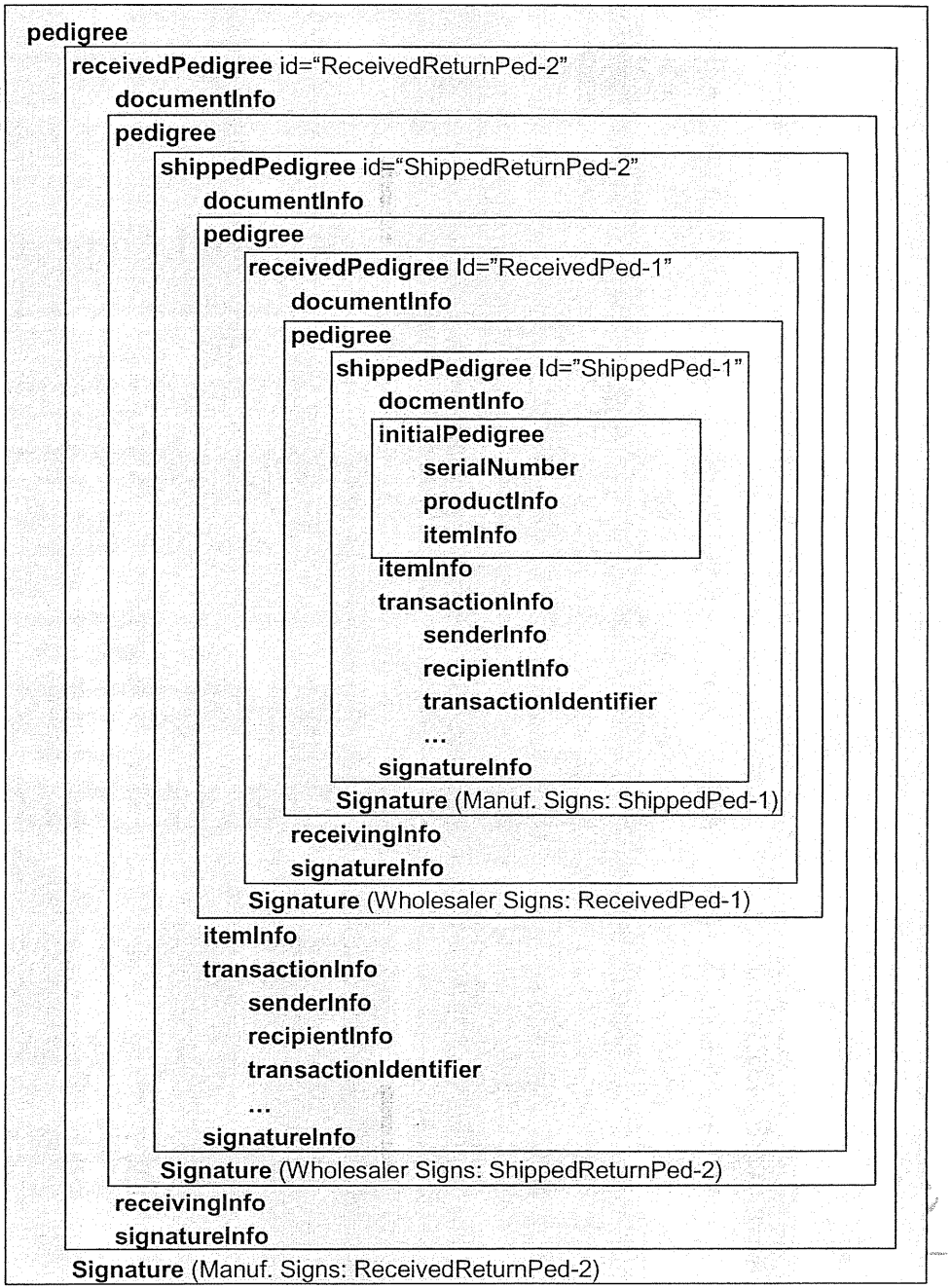
GS1 EPCglobal

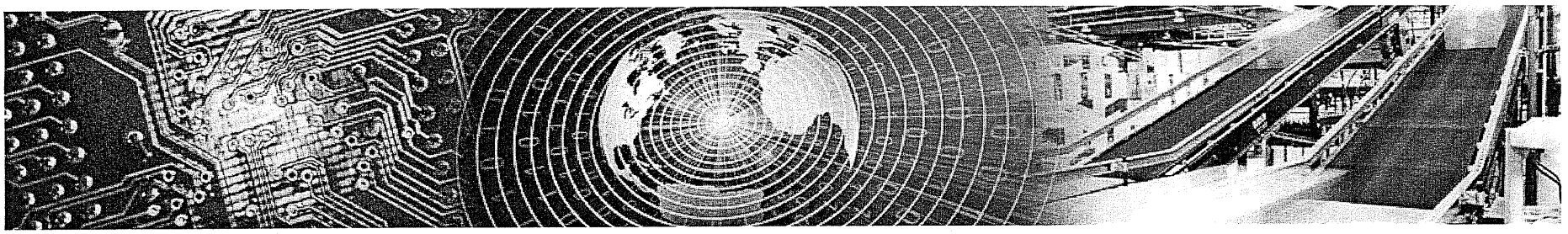


Shipped and Recei

Pedigree with return transaction

(initiated by manufacturer, received and signed inbound by wholesaler, return transaction applied by wholesaler for manufacturer return and signed outbound, received and signed inbound by manufacturer)





Shipped and Received Pedigree Components

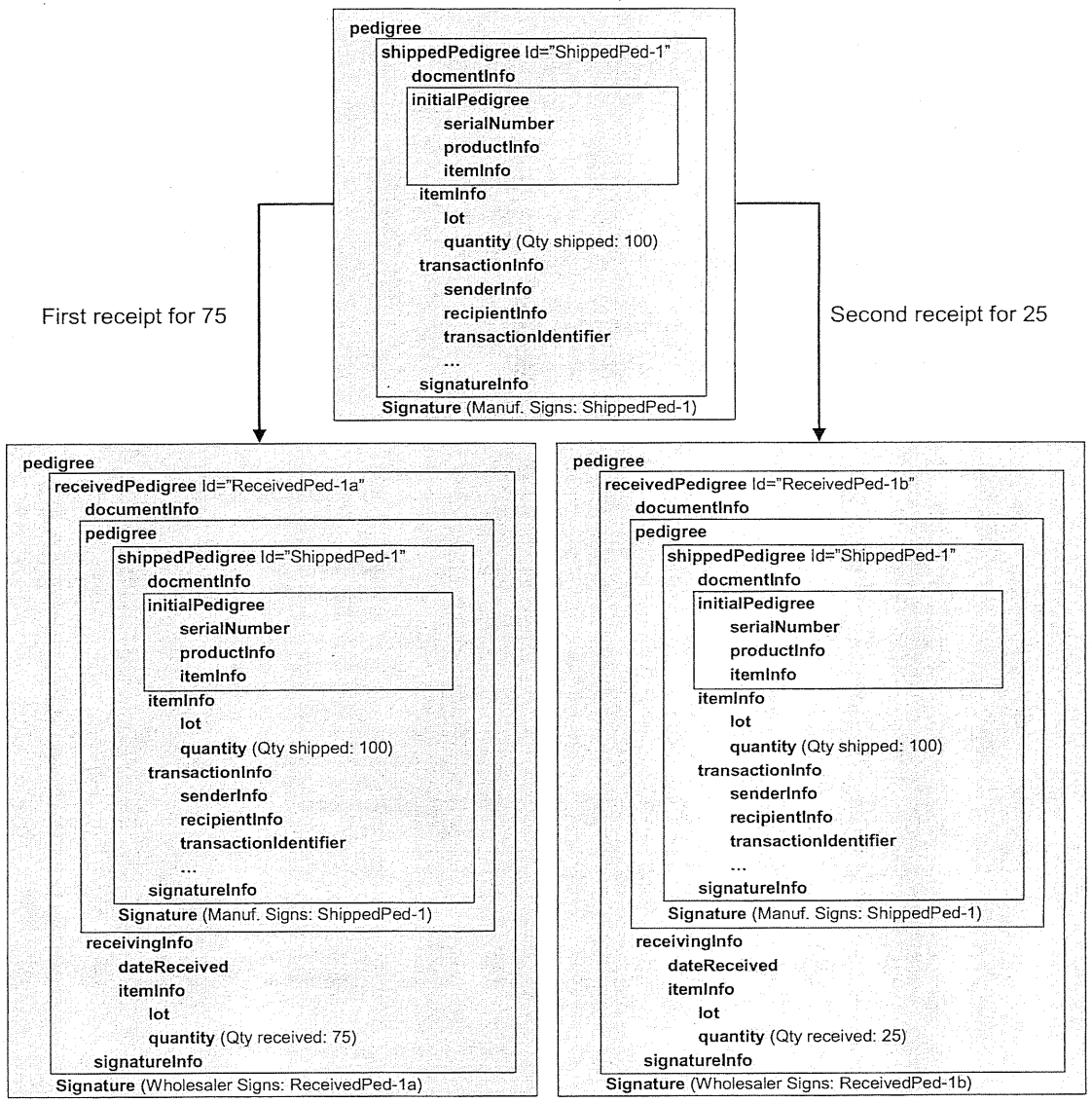
The following diagrams illustrate the different forms a complete pedigree may take when pedigrees are exchanged between trading partners.

GS1 EPCglobal

Usage Guidelines for Creating and Appending Information to Pedigrees

Partial Receipt of Products against Pedigree

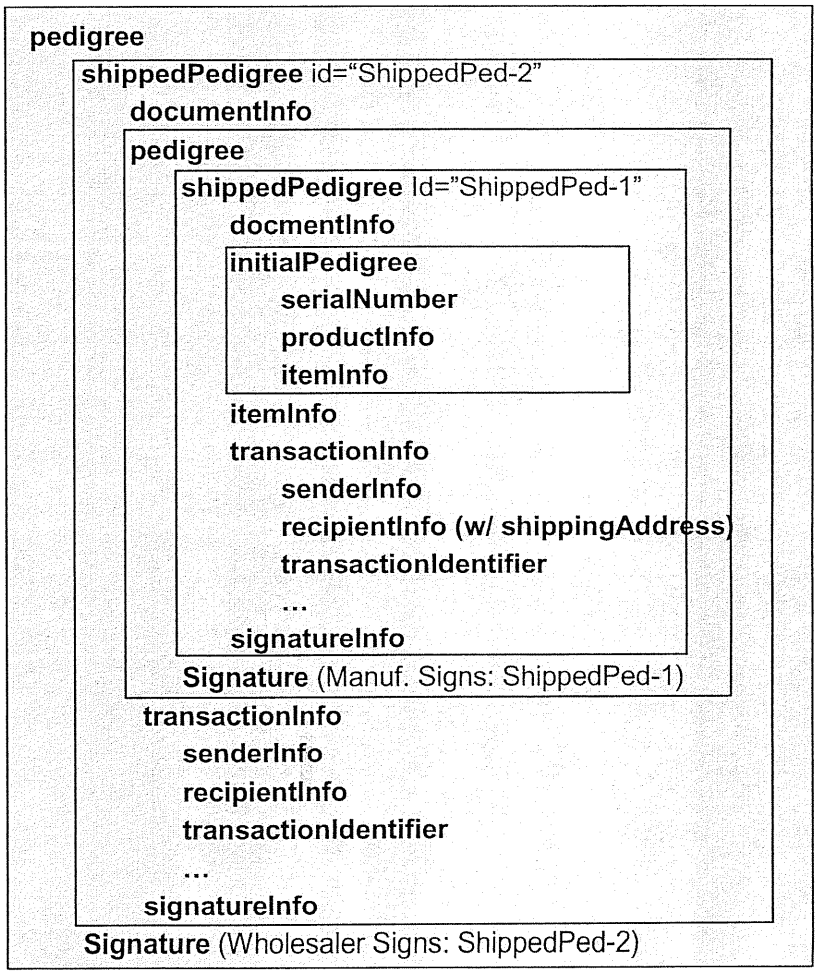
The partial receipt of product against pedigree is described for a sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. The wholesaler receives the products in two partial shipments and updates each partial receipt against the original pedigree, resulting in a new received pedigree for each partial receipt.



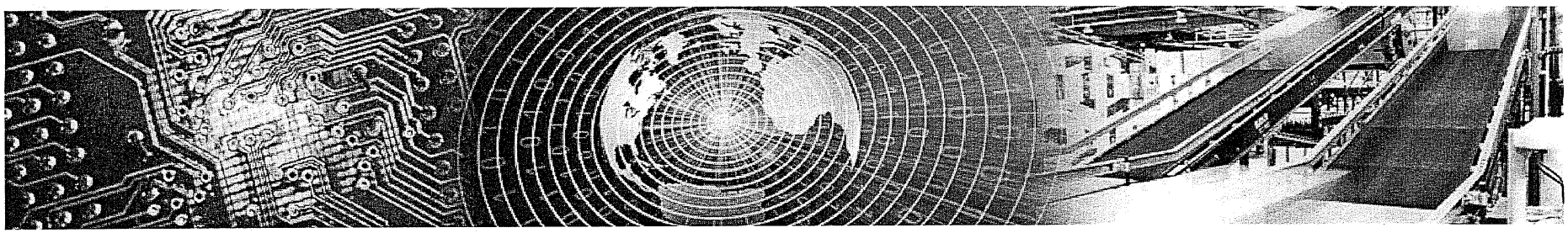
Usage Guidelines for Creating and Appending Information to Pedigrees

Pedigree Flow for a Manufacturer-initiated Drop Ship

The pedigree flow is described for a drop ship transaction brokered by wholesaler, where pharmacy purchases the product from the wholesaler, but the manufacturer ships the product directly to the pharmacy. In this scenario, the manufacturer initiates the start of the drop ship pedigree documenting the sales transaction from the manufacturer to the wholesaler with the shipping information indicating the direct shipment to the pharmacy. The wholesaler adds only the second part of the drop ship transaction to the pedigree documenting the sales transaction from the wholesaler to the pharmacy.

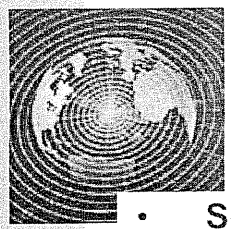


GS1 EPCglobal



Pedigree Scenario Walk Through

GS1 EPCglobal



EPCglobal Pedigree Prototype Event

Scenarios – Trace Scenarios

- **Scenario 1:** This scenario depicts the pedigree flow for the sale of a serialized product from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. The wholesaler then sells and ships one of the product items to a pharmacy DC.

Not Applicable in California

Scenario 2: This scenario depicts the sale of a non-serialized product from a wholesaler to a retail pharmacy DC, when no pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.

Not Applicable in California

Scenario 3: This scenario depicts the sale from a wholesaler to a retail pharmacy DC, when a paper pedigree is provided by the manufacturer and the wholesaler initiates the pedigree.

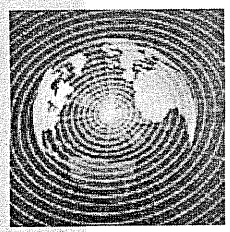
- **Scenario 4:** The pedigree flow is described for a sale from a repacker to a wholesaler, where the repacker initiates the pedigree for a repackaged item. The repack pedigree contains the pedigree for the source product used to create the repack products

- **Scenario 5**: This scenario depicts the kitting of several products and the subsequent sale from a kit manufacturer to a wholesaler.

- **Scenario 6**: This scenario depicts the partial receipt of product for sale from a manufacturer to a wholesaler, when the manufacturer initiates the pedigree. It then includes another transaction from one wholesaler to another, which depicts the receipt of a pedigree without signing the pedigree on inbound receipt. The pedigree is subsequently signed on the next outbound transaction to the retail pharmacy.

Not Applicable in California

Scenario 7: This scenario depicts the pedigree flow for the sale of a non-serialized product from a manufacturer to a wholesaler, when the wholesaler initiates the pedigree. The wholesaler then sells and ships the product to a pharmacy DC, then the pharmacy DC returns the product to the wholesaler. Then the wholesaler sells and ships the product to another pharmacy DC. This pharmacy DC also returns the product to the wholesaler.



EPCglobal Pedigree Prototype Event

Scenarios (cont.)

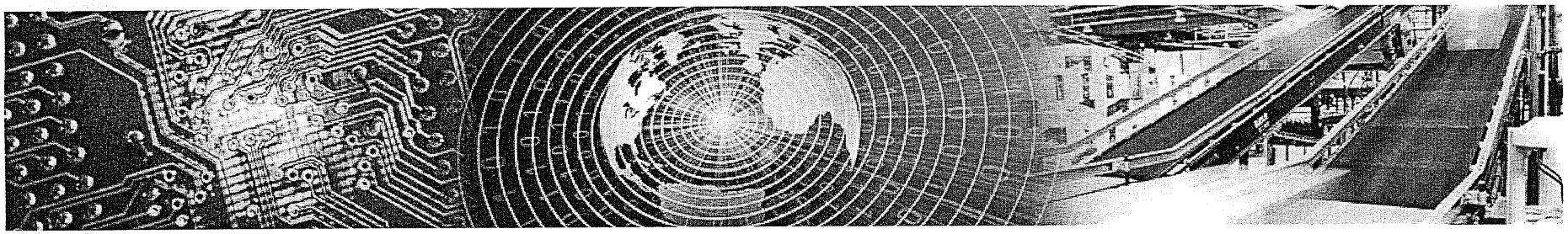
The following are "Track" Scenarios and are <u>not supported</u> by the current Pedigree standard.

Not Supported by Current Standard

- **Scenario 8:** This scenario depicts the ability for a company to identify the location of all the units of a particular NDC/lot or a particular EPC at downstream trading partners that they have sold product to in order to support faster recalls.

Not Supported by Current Standard

- **Scenario 9:** This scenario depicts the ability for a company to see the aggregate inventory levels and product movement of all of a particular NDC/lot at downstream trading partners that they have sold product to in order to support more effective forecasting & replenishment.



Proposed Pedigree Certification Testing

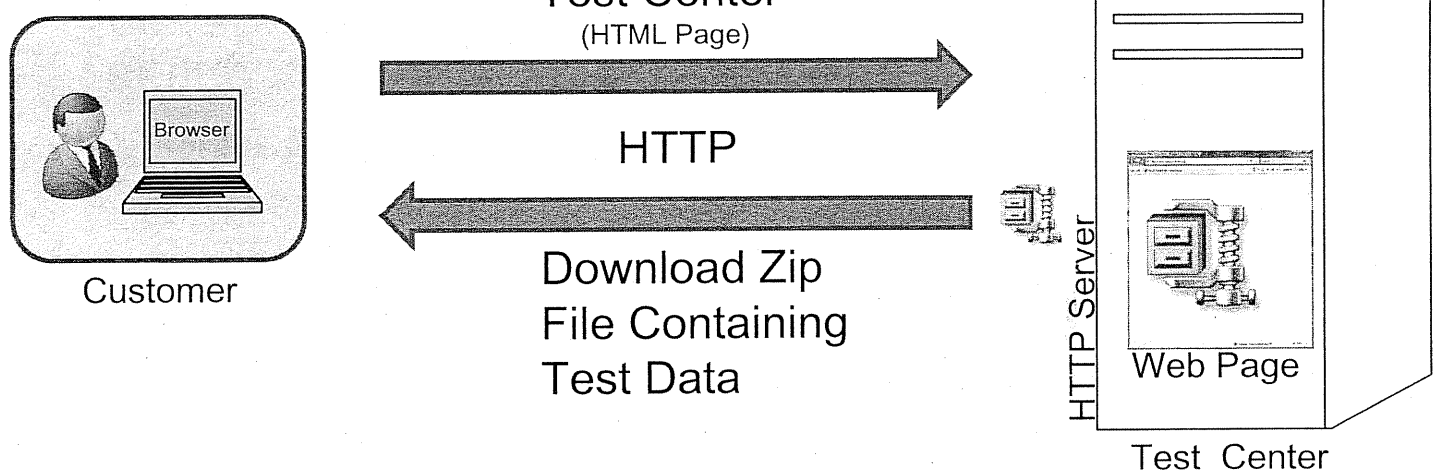
Draft as of 2/9/2007

GS1 EPCglobal

Overview

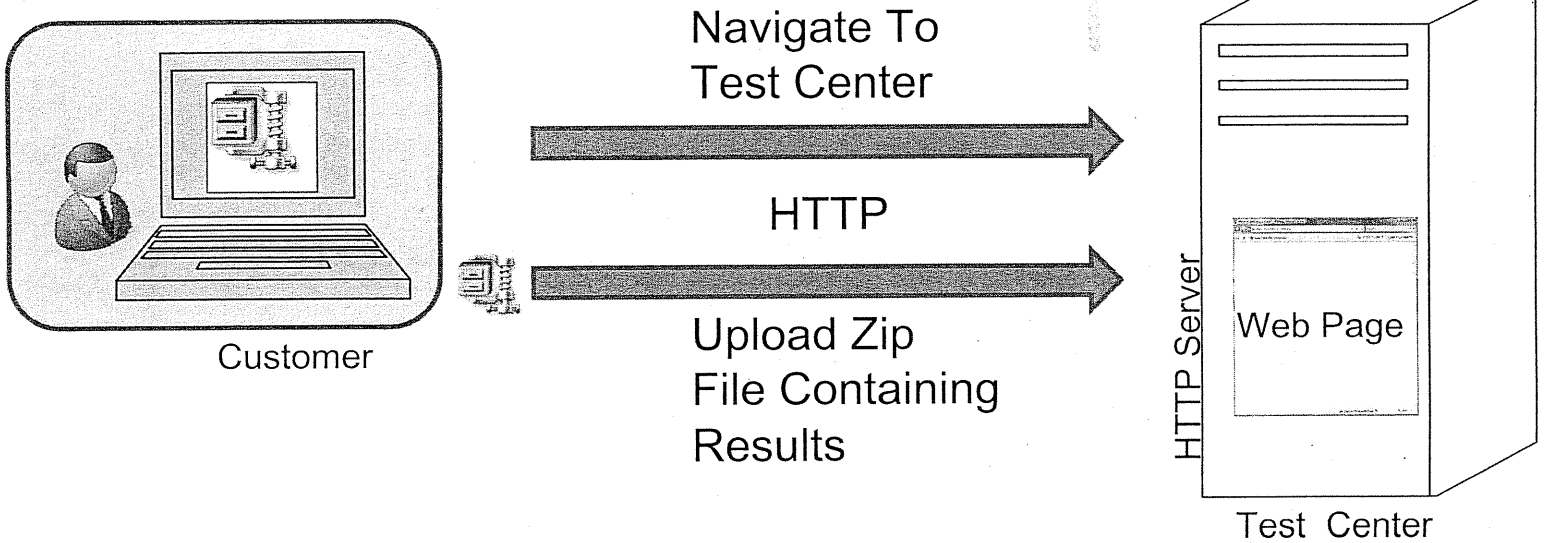
- Test conducted remotely
- Test data downloaded by IUT from Testing Center Web Site as a zip file
  - Test data includes test data and X.509 certificates issued by Testing Center that acts as Certificate Authority
  - Each Pedigree layer is signed using a different certificate. Testing Center tells IUT which certificates to use for each test ie certA, certB, etc (see slide 4)
- IUT uploads results to Testing Center Web Site
- Testing Center checks result files automatically against Test Scenarios and Test Matrix

Taking the Test

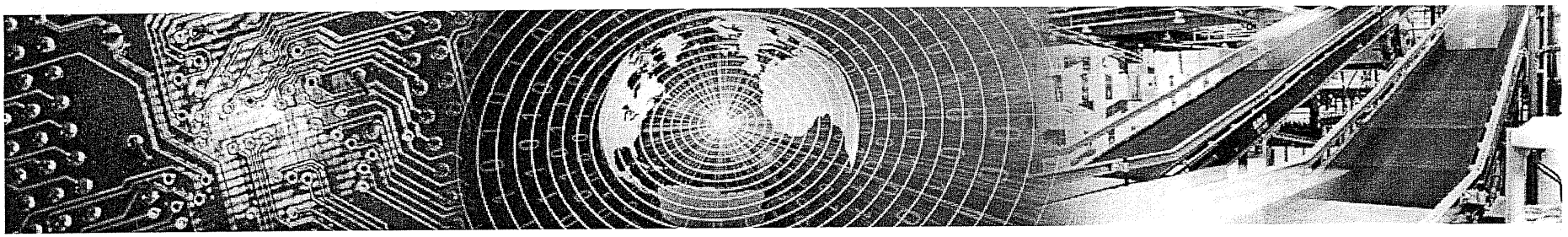


GS1 EPCglobal

Submit Test

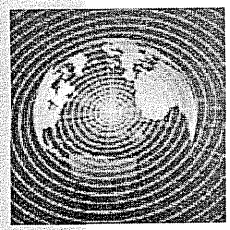


GS1 EPCglobal



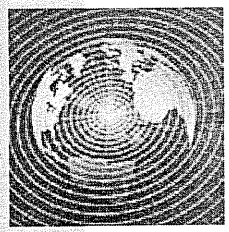
Follow-up Items
from Pedigree review meeting

GS1 EPCglobal



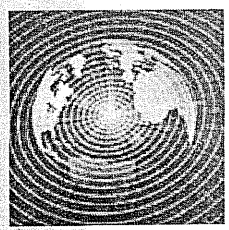
Pedigree Review Follow-up

1. Unit Dose Serialization
2. Partial Shipments
3. Drop Shipments
4. Signature and Certification of in-bound shipments
5. Return of saleable product to Mfgr by Whlsr and later resold by Mfg.
6. Pedigree status for intra-company transfers into CA.
7. Voided Pedigrees
8. Inference



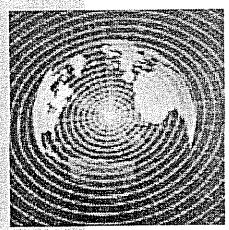
Pedigree Review Follow-up

CA BoP Follow-Up Items	Potential Assignment EPCglobal / Industry	Suggested Approach
1)Unit Dose Serialization	**Mfgrs:** Probability of serializing sub-units?	**Mfgrs:** PhRMA survey, results aggregated
Mfgrs SKUs comprised of sub-units (eg. 10-pack pre-filled syringes), maybe broken-down, where sub-units are sold as eaches. What are the implications re: serialization? What is the impact to repackagers? How will repackagers continue the pedigree?	**Whlrs:** % of Mfgrs' SKUs sold in sub-units?	**Whlrs:** HDMA survey, results aggregated
	Rtlrs:	**Rtlrs:**
	EPCg: How many levels of serial #s does the standard support?	**EPCg:**



Pedigree Review Follow-up

CA BoP Follow-Up Items	Potential Assignment EPCglobal / Industry	Suggested Approach
2) **Partial Shipments**	**Mfgrs:** % of orders partially shipped?	**Mfgrs:** PhRMA survey, results aggregated
Orders are not always shipped complete & will likely have pedigree implications. How often does this occur? What pedigree /business process changes may be required?	**Whlrs:** % of orders partially shipped?	**Whlrs:** HDMA survey, results aggregated
	Rtlrs: % of partial shipments received?	**Rtlrs:** NACDS survey, results aggregated
	EPCg: Evaluate standard to determine how best Drop shipments can be handled.	**EPCg:** Convene Pedigree Messaging SMEs to evaluate the standard against this condition.



Pedigree Review Follow-up

CA BoP Follow-Up Items	Potential Assignment EPCglobal / Industry	Suggested Approach
3) Drop Shipments	**Mfgrs:** % of orders dropped shipped?	**Mfgrs:** PhRMA survey, results aggregated
Mfgrs. ship certain products to the end-customer, but billing goes through the Wholesaler. Where should the pedigree be sent and what transaction information should it reflect?	**Whlrs:** % of orders billed as dropped shipped?	**Whlrs:** HDMA survey, results aggregated
	Rtlrs: % of partial shipments received?	**Rtlrs:** NACDS survey, results aggregated
	EPCg: Evaluate standard to determine how best Drop shipments can be handled.	**EPCg:** Convene Pedigree Messaging SMEs to evaluate the standard against this condition.

Pedigree Review Follow-up

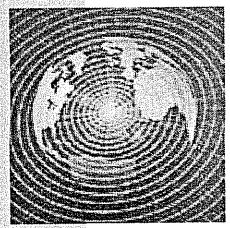
CA BoP Follow-Up Items	Potential Assignment EPCglobal / Industry	Suggested Approach
4) **Sign & Cert. of In-bound shipments**	**Mfgrs:** No Action Required	**Mfgrs:** No Action Required
The Law, as written, would require signature & certification of in-bound shipments, as well as out-bound. Use of inference on in-bound would be prohibited under strict interpretation of the Law.	**Whlrs:** No Action Required	**Whlrs:** No Action Required
	Rtlrs: No Action Required	**Rtlrs:** No Action Required
	EPCg: No Action Required	**EPCg:** No Action Required

Pedigree Review Follow-up

CA BoP Follow-Up Items	Potential Assignment EPCglobal / Industry	Suggested Approach
5) **Return of saleable product to Mfgr by Whlsr and later resold by Mfg.**	**Mfgrs:** % of returned product accepted back into inventory?	**Mfgrs:** PhRMA survey, results aggregated
There are times when saleable product is returned by the Whlsr to the Mfgr and may be re-sold by the Mfgr. How should a pedigree treat this transaction? Should it reflect the return trip to Mfgr or should it be start anew when the product is re-sold by the Mfgr?	**Whlrs:** % of saleable product returned to Mfgr.	**Whlrs:** HDMA survey, results aggregated
	Rtlrs:	**Rtlrs:** NACDS survey, results aggregated
	EPCg: Evaluate standard to determine if pedigree can either reflect return leg to manufacturer and addition of new recipient information when returned product is re-sold?	**EPCg:** Convene Pedigree Messaging SMEs to evaluate the standard against this condition.

Pedigree Review Follow-up

CA BoP Follow-Up Items	Potential Assignment EPCglobal / Industry	Suggested Approach
6) **Pedigree status for intra-company transfers into CA.**	**Mfgrs:** No Action Required	**Mfgrs:** No Action Required
Product sold to a Whlrs to an out-of-state location that does not require Mfgr. originated pedigree may be intra-company transferred to CA. What are the CA pedigree implications?	**Whlrs:** % of product intra-company transferred from out-of-state to CA?	**Whlrs:** HDMA survey, results aggregated
	Rtlrs: No Action Required	**Rtlrs:** No Action Required
	EPCg: No Action Required	**EPCg:** No Action Required

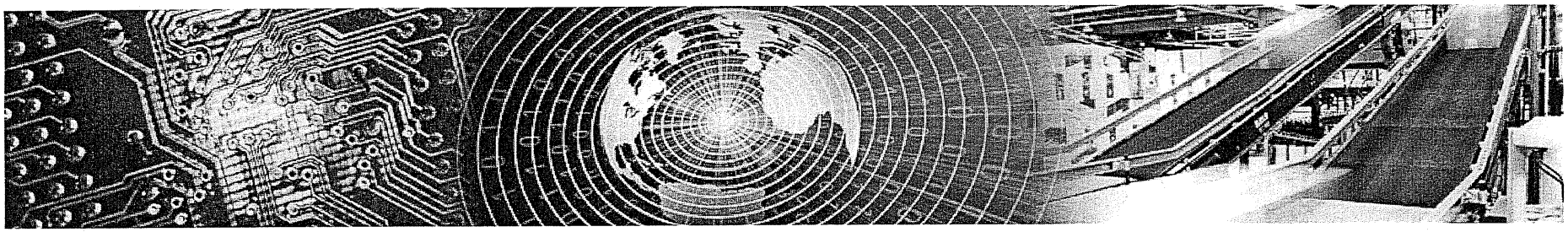


Pedigree Review Follow-up

CA BoP Follow-Up Items	Potential Assignment EPCglobal / Industry	Suggested Approach
7) **Voided Pedigrees**	**Mfgrs:** No Action Required except for product destruction	**Mfgrs:** PhRMA develop recommendation
What is the process of voiding pedigrees where either an error in the pedigree has occurred (e.g. typographical error), or product has been returned? How are pedigrees for products marked for destruction managed?	**Whlrs:**	**Whlrs:**
	Rtlrs: No Action Required	**Rtlrs:** No Action Required
	EPCg: Evaluate standard to determine how best pedigrees can be voided to correct errors or returned goods.	**EPCg:** Convene Pedigree Messaging SMEs to evaluate the standard against this condition.

Pedigree Review Follow-up

CA BoP Follow-Up Items	Potential Assignment EPCglobal / Industry	Suggested Approach
8) **Inference** – what is the industry's view on inference? How would it work? Is there a time limit from in bound receipt inference until all unique ID numbers have been certified?	**EPCg:** Complete Inference whitepaper	



Questions?

GS1 EPCglobal

Attachment 5

AmerisourceBergen's Presentation at the March 21, 2007 Meeting

AmerisourceBergen

AmerisourceBergen:
Track And Trace Pilot Update

California Board of Pharmacy
March 21,2007

AmerisourceBergen

Objective:

- Provide webinar survey data
- Provide pharmaceutical industry educational data based information

Webinar Survey Data:

Who participated:

- 178 total participants
- 82 different companies/organizations
- 80% were pharmaceutical manufacturers

US pharmaceutical product represented:

- 32% of Rx SKU's sold in US
- 37% of Rx units sold in US
- 38% of Rx dollars sold in US

Webinar Survey Data:

Method of serialization:

- 73% were undecided as to how their companies were going to serialize product
- 19% RFID
- 9% 2D barcode

Percent of SKUs that could be serialized by 2009:

- 18% stated that between 50 – 100 % of SKUs
- 27% stated less than 50% of SKUs
- 9% stated 0% of SKUs
- 45% did not answer

Webinar Survey Data:

Interested in additional information:

- 73% Track and Trace with EPCIS and Registry
- 72% product serialization
- 74% Track and Trace with EPCIS and Registry and product serialization

Pilot Engagement:

Additional information requested:

- 9 manufacturers
- Building business use cases for pilot activity

ABC Industry Education:

- Provide data to help make UHF / HF determination.
- Item specific survey regarding scan rates.
- Tote mix and tote content data regarding scan rates.
- Data transmission rates.
- Non-line of site process comparison.

ABC Long Term Commitment:

- Build infrastructure that streamlines data sharing and that contributes to patient safety and business efficiency.
- Enable data sharing for multiple use cases.

Thank you

Attachment 6

SupplyScape's Presentation to the Enforcement Committee on March 21, 2007

Industry Adoption of EPCglobal Drug Pedigree Messaging Standard

Lucy Deus, VP Product Development, SupplyScape

California Board of Pharmacy
Enforcement Committee
March 21, 2007

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Agenda

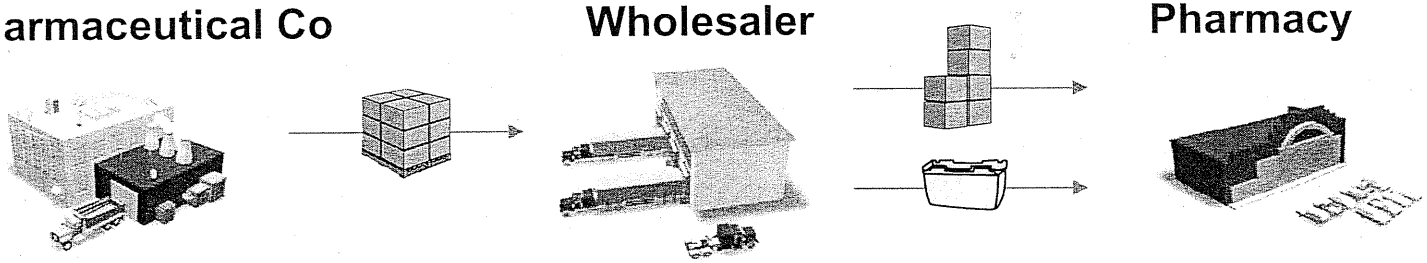
- EPCglobal Drug Pedigree Standard Adoption
- Characterization of Pedigree Deployments
- Strategic Benefits that can be Realized from Pedigree
- Summary

EPCglobal Drug Pedigree Standard Adoption

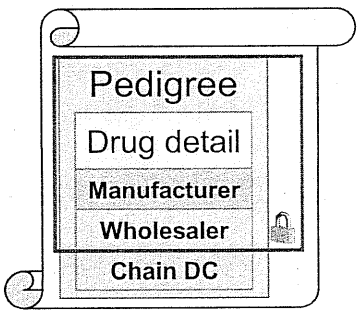
- Interim version of EPCglobal Pedigree Standard in use by industry for the past year for electronic pedigree implementations nationwide
  - Implementations since early 2006
  - Supporting state-level and nationwide pedigree implementations
- Ratified version is a "minor release" update to the standard
  - Backwards compatible with the Interim version used by industry today
- Adoption statistics across state and national use
  - More than 45 companies have/are deploying electronic pedigree and EPC authentication solutions from SupplyScape Corporation
  - Over 200 million drug products secured with electronic pedigrees today

E-Pedigree Flow Using EPCglobal Pedigree Standard

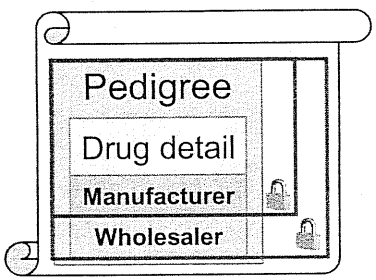
Pharmaceutical Co **Wholesaler** **Pharmacy**

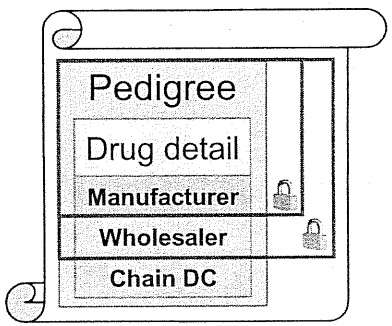


Pedigree Today



California E-Pedigree





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Characterization of Current Pedigree Deployments

Pedigrees initiated primarily by:	• Wholesalers • Repackers • Kitters
Pedigrees received by:	• Wholesalers • Repackers • Kitters • Pharmacy DCs • Chain and independent pharmacies • Hospitals and clinics
Pedigrees for endpoints managed by:	• Pedigree portals offered by ▪ Pharmacy DCs to their retail stores ▪ Wholesale distributors to their customers • Requires only basic web access at endpoints
Pedigrees tracking products at:	• Mostly lot and/or case level • Serialization not widely implemented
Pedigree solutions created by:	• Mostly vendor pedigree offerings • Some "home grown" pedigree implementations • Using EPCglobal interim standard for interoperability

Initial E-Pedigree Adoption Learnings
Selected Examples

- Internal implementation within a company
  - Business process re-work to accommodate pedigree
  - Software deployment and integration
- Trading partner coordination and interoperability testing
- Portal for end-points
- Rules are needed to help guide industry
  - Requirements need to be well defined
  - Once Rules are finalized, industry needs time to prepare/adjust

Pedigree Data Management System Enables Data Leverage for Business Value

Pedigree Transaction Data

Product Information

AllergyMed
Kendall Pharmaceuticals
65 mg, 90 tablets
NDC 09781032401 (1)

Pedigree Serial Number

(2) 406288152341b123b123faed8129023333

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▸ History of Drug Sales and Distributions

SELLER	TRANSACTION	BUYER	TRANSACTION IDENTIFIER	TRANSACTION DATE
1 Kendall Pharmaceuticals	sale	Rx Wholesaler Inc	RWS-66825473	19 Aug 2006

Seller: Kendall Pharmaceuticals
500 Manufacturer Road, West Hills, CA 91304
USA

License Number: 31.73651, CA

Transaction Identifier: Invoice RWS-66825473, 19 Aug 2006 (7)

Authentication Contact: Armando Authenticator
555-123-4567, auth@kendallpharma.com
https://rxauthentication.kendallpharma.com

Certified By: Mike Manufacturer, Compliance Lead, 19 Aug 2006

Buyer: Rx Wholesaler Inc
305 Wholesaler Place, Madison, IN 47250 USA

Shipped To: Rx Wholesaler Inc
200 Warehouse Road, Madison, IN 47250 USA

License Number: 46.11896, IN

Date Received: 21 Aug 2006

Received and Authenticated By: Wendy Wholesaler, Quality Manager, 21 Aug 2006

ITEMS IN TRANSACTION (3) (4) (5)

Lot A231444 Expiration 15 Dec 2008 Quantity 3
01.0000978.000324.1005536707 01.0000978.000324.1005536708 01.0000978.000324.1002526701 (6) (8)

SELLER	TRANSACTION	BUYER	TRANSACTION IDENTIFIER	TRANSACTION DATE
2 Rx Wholesaler Inc	sale	ABC Pharmacy Inc	ABC-01-09834563	11 Sep 2006

Seller: Rx Wholesaler Inc
200 Warehouse Road, Madison, IN 47250 USA

License Number: 46.11896, IN

Transaction Identifier: Purchase Order ABC-01-09834563, 11 Sep 2006

Authentication Contact: Vinny Verify
555-123-4567, verify@rxwholesaler.com

(10) Certified By: William Wholesaler, Manager, 11 Sep 2006

(9) Buyer: ABC Pharmacy
600 Pharmacy Road, Tampa, FL 33604

License Number: 72.01401, FL

Date Received: 12 Sep 2006

Received and Authenticated By: Phil Pharmacy, Pharmacy Supervisor, 12 Sep 2006

ITEMS IN TRANSACTION

Lot A231444 Expiration 15 Dec 2008 Quantity 2
01.0000978.000324.1005536707 01.0000978.000324.1005536708

- ✓ Counterfeit
- ✓ Diversion
- ✓ Recalls
- ✓ Availability
- ✓ Returns Reconciliation
- ✓ Chargeback Reconciliation
- ✓ Rebate Reimbursement
- ✓ Shelf-life Management

Business Leverage

Product and Transaction Specifics
1) Product ID #
2) Serialized Product Title
3) Lot #
4) Expiration Date
5) Exact Quantity
6) Product Serial #
7) Related Info (PO, Invoice)
8) Transaction Date
9) Trading Partner Identification
10) Transaction Validation

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Pharmacy Chains Leverage Pedigree for Business Value

- Business Goals: Regulatory compliance and Operational efficiency
  - Platform for pedigree regulatory compliance (Florida first, Nationwide phased)
  - Streamline product handling between Trading partners, Pharmacy DCs and Stores
- Pedigree Compliance
  - Pedigrees received from upstream trading partners *or*
  - Pedigrees created if direct shipments from manufacturers
  - Pedigrees maintained by Pharmacy DCs – retrievable by individual stores
- Streamlined Product Handling
  - Pedigree information leveraged to improve DC operations
  - Maintain distribution speed even with increased data handling
    - Automatic pedigree authentication upon receipt
    - Process improvements based on knowledge of upcoming shipments
    - Enhanced automation even with variety of trading partner technical capabilities
- Operational and Business Value analysis
  - Pedigrees leveraged for receiving improvement, internal inventory tracking control
  - Pedigree data analyzed for shelf-life management and secure sourcing control

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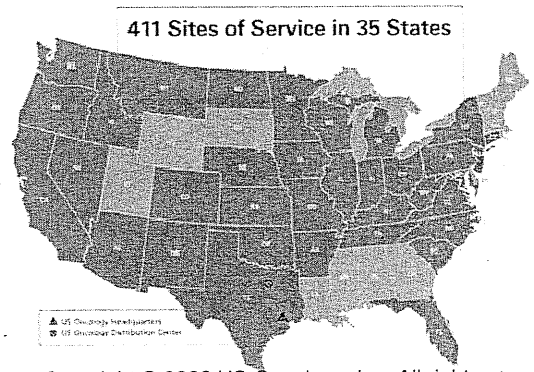
Specialty Distributor Leverages Pedigree for Business Value



- US Oncology: One of the nation's largest oncology services networks
  - 550,000 patients per year undergoing treatment
  - $1.7B in drugs
- First oncology distributor to provide E-Pedigrees
  - Implemented SupplyScape E-Pedigree initially for Florida compliance and expanded to nationwide pedigree in 2006
  - Provides Pedigree Portal for hundreds of oncology practice end-points
- Pedigree data enabled rapid and precise product recall
  - US Oncology alerted by manufacturer of recall of two lots of Methotrexate, a cancer treatment drug
  - Leveraged pedigree data to rapidly locate recalled product
    - Product was tracked to 6 specific practices within minutes
    - Practices contacted with product details to isolate and return product
    - Recall process made fast and simple compared to the traditional process
  - Rapid and precise recall enabled by the ability to track specific drug product through supply chain and trace exact journey via secure pedigree data

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Future Considerations for Evolving Pedigree Standards

As pedigree adoption grows and standards evolve, some key requirements should be preserved and considered…

- Operational Support
  - Compatibility with existing standards
  - Workable migration strategies to new capabilities
  - Well-defined use cases across industry that inform the standards
  - Industry validation through wide adoption in diverse environments
  - Strong security that ensures integrity and non-repudiation of the data and supply chain
  - Scalability, reliability and availability
  - Cost-effective for all supply chain participants
- Regulatory Support
  - Continue to maintain compliance with existing and emerging laws
  - Capability to meet regulatory timelines
- Business Value
  - Ability to derive business and operational value

EPCglobal Pedigree Standard Adoption Summary

EPCglobal Drug Pedigree Standard – Supporting Regulatory and Industry Requirements

Regulatory

- Supports data elements for all known state and federal pedigree laws
- Supports serialized items, serialized cases and non-serialized items

Format, storage and transmission

- Pedigree data expressed in a secure portable XML exchange format
- Lends data to be highly compressible while maintaining data security

Security

- Detection: Integrity and non-repudiation so that pedigree data can be trusted

Use Cases

- Extensive set of use cases for complete regulatory / business support

Adoption

- Developed by industry stakeholders and solution providers
- Providing interoperability for more than 45 companies adopting electronic pedigrees across state and national levels

Leverage for strategic business value

- Leverage pedigree data both within four walls and across the value network
- Enable applications such as shelf life management, recall processing, returns and chargeback reconciliation, fraud and diversion detection, etc.

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Attachment A

Meeting Summary of the Enforcement Committee and the Work Group on E-Pedigree March 21, 2007

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Enforcement Committee and Workgroup on E-Pedigree
MEETING SUMMARY

Date: March 21, 2007

Location: Red Lion Hotel
1401 Arden Way
Sacramento, California 95815

Board Members Present:
Bill Powers, Board President and Chairperson
Ruth Conroy, PharmD, Board Member
Stanley Goldenberg, RPh, Board Member
Rob Swart, PharmD, Board Member

Staff Present:
Virginia Herold, Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joan Coyne, Supervising Inspector
Joshua Room, Deputy Attorney General
Anne Sodergren, Legislation and Regulation Manager
Karen Abbe, Public and Licensee Education Analyst

Call to Order

Chairperson Powers called the meeting to order at 9:35 a.m.

Mr. Powers advised that there was a change to Agenda Item 1c. The Proposed Modified Disciplinary Guidelines for the Board of Pharmacy would not be discussed at this meeting due to a printing error. This item will be placed on the agenda for the next Enforcement Committee meeting.

1. Enforcement Committee

a. Letter of Concern to CMS regarding the Federal Deficit Reduction Act's Use of Average Manufacturers' Cost as Reimbursement Base for Medications for Medicaid Patients

At the January 31, 2007 Board Meeting, the board voted to submit written comments to the Centers for Medicare & Medicaid Services (CMS) regarding their proposal to based Medicaid reimbursement on average manufacturer price. The board's concern was that this policy would lead to limited patient access due to pharmacies withdrawing from the Medicaid program if reimbursement costs are less than pharmacy costs to buy the medications.

Mr. Powers stated that a copy of the letter sent from the board to CMS dated February 16, 2007 was included in the committee meeting materials packet.

b. Proposal to Develop an Ethics Course for Pharmacists, Modeled After the Experiences of the Medical Board of California In Establishing an Ethics Course for Physicians

At the January 31, 2007 Board Meeting, the board directed that a small work group be formed to perform an in-depth review of a proposal to develop an ethics course for pharmacists which could be used as a term in disciplinary decisions. Some of the topics the board directed this work group to review included recommendations of the types of violations that could warrant a probation condition of completing an ethics course, consideration of the experiences of the Medical Board, and generally, to look at the proposal and components more fully.

The board directed that a report of this review be provided at the June 20 and September 20 Enforcement Committee meetings, and at the October 2007 Board Meeting.

Mr. Powers stated that one board member, Susan Ravnan, had volunteered to serve on the work group. At today's meeting, board member Robert Swart volunteered as well, so there are now two board members on the subcommittee. Mr. Powers asked if there was any discussion on the matter, and there was none.

c. Proposed Modified Disciplinary Guidelines for the Board of Pharmacy

Mr. Powers restated that Agenda Item 1c would not be discussed today due to a printing error. This item will be placed on the agenda for the next Enforcement Committee meeting.

d. Enforcement Committee Strategic Plan Update for 2007-08

In July 2006, the board finalized its strategic plan for 2006-2011. Each year in the spring, the board revises the strategic plan to keep it current.

Ms. Herold stated that at the April 2007 Board Meeting, the board will review any modifications to the strategic plan recommended by each committee for the development of the 2007-08 strategic plan. At this time, the Enforcement Committee has the opportunity to revise its strategic plan, and the materials in the committee

packet reflect the last committee update provided at January 31, 2007 Board Meeting. She suggested that the plan be updated to add activities underway or completed by the committee: analysis of an enforcement option of an ethics course, and a letter to CMS and DEA encouraging them to alter the process by which prescriptions are written or reimbursed. With the three changes, all activities will be included in the strategic plan.

Mr. Powers asked if there was any discussion on the matter. There were no comments from the board or from the public. Dr. Swart made a motion to accept the three suggested changes.

MOTION: That the Board of Pharmacy update the Enforcement Committee's Strategic Plan for 2007-08 to add the option of an ethics course, and a letter to CMS and DEA.

M/S: SWART/CONROY

SUPPORT: 4 OPPOSE: 0

2. Comments by the FDA on the Implementation of the Prescription Drug Marketing Act (PDMA) Provisions Involving Pedigrees

In June 2006, the FDA indicated it would implement PDMA pedigree requirements for medicine sales that occur outside the authorized distribution channel. The requirements would be in force beginning December 2006. However, just prior to December 2006, a U.S. District Court Judge in the Eastern District of New York issued a written order granting a preliminary injunction enjoining the FDA from implementing one section – 21 CFR 203.50(a). Section (a) specifies the type of information that must appear in the pedigree.

The committee's meeting materials for this meeting included the ADDENDUM to FDA's Guidance for Industry: PDMA Pedigree Requirements – Questions and Answers Related to the Preliminary Injunction ordered 12/5/06 in RXUSA Wholesalers, Inc. v. HHS (dated 12/15/06).

Ilisa Bernstein, PharmD, JD, Director of Pharmacy Affairs, FDA, Office of the Commissioner/Office of Policy, provided an update via speakerphone regarding the FDA's pedigree requirements. She also spoke about FDA studies underway with respect to RFID tagging on liquid products.

Dr. Bernstein thanked the committee for inviting her to speak. She said she last spoke with the committee before the regulations went into effect. The FDA was sued on some of the regulation provisions resulting in the court issuing a preliminary injunction until December 8, 2007, when all the regulations will go into effect. The injunction prohibits the FDA from implementing 21 CFR 203.50(a) at this time.

In summary, 21 CFR 203.50(a) says that each sales transaction must be included on the pedigree; that provision and others are subject to the preliminary injunction. The FDA intends to send the regulations and notice of appeal to court so that pedigrees must include information going back to the manufacturer. Though the injunction was from the Eastern District of New York, drugs pass through interstate commerce. The preliminary injunction does not affect the requirement that pedigrees must go back to the last authorized distributor of record (ADR).

Dr. Bernstein stated that the bulk of the policy guide she spoke of in December is still in effect until December 1, 2007 (i.e., who is an ADR). Those regulations should be undertaken as well as 203.50(b), (c), and (d), which are part of PDMA and are still in effect. Under the injunction, pedigrees must only go back to the last ADR, but it's in the best interest for pedigrees to go back to the manufacturer.

Dr. Bernstein said she was limited in what she could talk about regarding the lawsuit, but could talk about the studies initiated by the FDA several years ago regarding RFID. The FDA asked manufacturers what affect radio frequency had on the integrity and stability of drug products. The FDA heard back about some theoretical effects, but no hard data was presented. The FDA's Center for Devices (along with the Center for Drugs) subsequently asked their lab to look at identified products and packaging. They developed an exposure system using RFID technology in order to determine whether there is any effect. Data was gathered, and an analysis of that data will be prepared. The FDA's labs have competing priorities for their resources, but the analysis will be forthcoming. At this time, the FDA cannot predict what the data will reveal.

Mr. Goldenberg asked what would the FDA require (regarding pedigrees) during an inspection of a pharmacy.

Dr. Bernstein replied that the enforcement of pharmacies is usually deferred to states, unless something comes to the FDA's attention.

Mr. Goldenberg asked whether small and large biotechnical proteins were part of the represented samples tested, and if so, which products were tested.

Ms. Bernstein replied that biotechnic proteins were part of the samples tested, but she did not have details to share about the samples taken.

Mr. Powers asked whether the FDA is auditing implementation of the new law and if an enforcement report would be issued.

Dr. Bernstein replied that enforcement and auditing are two different things. The FDA does have an enforcement program. The law and the regulations are in effect and enforcement is underway, but she couldn't specifically target where enforcement activities are being prioritized. She stated that the FDA issues enforcement

statistics, which talk about the numbers of inspections. The information is posted on their website.

Mr. Powers asked if there were any comments from the public. There were none. Dr. Bernstein was invited to stay on speakerphone to participate in the remainder of the committee meeting.

3. Workgroup on E-Pedigree

a. Status of the Progress of the EPCglobal Workgroup and Standards for Electronic Pedigrees

Since the last Enforcement Committee meeting, EPCglobal released its Ratified Pedigree Standard (January 2007). A copy of the press release was included in the committee meeting materials. The press release included a link to the website where the standard (138 pages) can be downloaded. Ratification of the standard is a major milestone for E-Pedigree.

Bob Celeste, EPCglobal, gave a presentation on the state of E-Pedigree and EPCglobal RFID Standards. Mr. Celeste stated that new information and some updates had been added to his presentation including pedigree requirements, supply chain registry, and tag decommissioning. A copy of the PowerPoint presentation is attached to this meeting summary.

Mr. Celeste spoke on several issues including work streams, item level tagging, serialization, drug expiration dates, lot numbers, track and trace, and high-frequency vs. ultra high-frequency. He stated that RFID is not required in order to produce E-pedigree. He emphasized that when referring to pedigree, you must look at:

1) the standard
2) the law you are trying to comply with

EPCglobal is now working on developing a standard for electronic track and trace; this standard is expected to be complete in the third quarter of 2007. Additional work is underway in the area of authenticating and decommissioning tags.

Mr. Goldenberg invited stakeholders to present their ideas and concerns to EPCglobal while the standards are being developed.

Dr. Swart requested that when updates are made to the EPCglobal charts, that arrows would show whether progress had stalled out in particular areas.

Mr. Celeste replied that most areas of development are in the 10-20 week stage, so he didn't show progress on the charts.

Mr. Powers asked for comments from any of the stakeholders and the public.

George Pennebaker stated that he was concerned that the pedigree tracking must be capable of capturing events that don't happen "often." He stressed that we must take care of problem issues, no matter how infrequently they happen, for example, what happens to the pedigree information when a wholesaler goes out of business. He also asked if the EPCglobal standard considers NCPDP standards. Mr. Celeste stated yes.

b. Summary of Meeting with EPCglobal on March 8, 2007

Mr. Goldenberg stated that he, President Powers, Virginia Herold, Judi Nurse, and Joshua Room met earlier in March with the nine representatives of EPCglobal. They walked through the messaging standard and various scenarios. A copy of the meeting summary is available in the meeting materials for this meeting. Information was provided including the fact that manufacturers destroy any drugs returned to them. He believes they are looking at minutia of detail, and they are also looking at "frequency of actions" to see how best to handle those infrequent occurrences.

The messaging standard developed by EPCglobal meets California's pedigree requirements.

Mr. Room stated that terminology must be agreed upon as they relate to E-Pedigree.

Dr. Swart asked how pedigree will be tracked into a new location when pharmacies consolidate.

Mr. Celeste replied that that will fall into the realm of due diligence when purchasing a company, including the products owned by those companies.

Mr. Room stated that it is important to determine whether pedigree will reflect change of ownership transactions, and whether it can be added onto pedigree.

John Valencia, representing a variety of pharmaceutical manufacturers, stated that the EPCglobal presentation was interesting, but asked if the board will move to adopt formal standards now that the law is revised and instituted. He stated that while interesting, the information is not binding.

Mr. Room clarified that there is no requirement for the board to adopt the standard. The board met with EPCglobal and indicated its interest in the standard, and it appears to include California's legal requirements. The standard itself is the industry's way to comply with the law.

Mr. Powers asked the FDA (via speakerphone) if they had any questions at this time; they had none.

c. Update by Manufacturers, Wholesalers and Pharmacies on Implementation of Electronic Pedigrees

Mr. Goldenberg stated that the board holds these quarterly public meetings as outreach programs to clarify the law and implementation strategies to licensees. If any stakeholders or anyone else that is interested has suggestions or wants to participate, they should contact Executive Officer Herold.

Mr. Powers called on Heather Zenk, a licensed pharmacist from Amerisource Bergen, to make a presentation on E-Pedigree.

Dr. Zenk stated that AmerisourceBergen is one of the three largest wholesalers. AmerisourceBergen gave a full presentation at the last work group on its electronic pedigree pilot project, and she would provide an update regarding what they had done since that meeting. A copy of this presentation is attached to this meeting summary.

Since the last meeting, Amerisource Bergen conducted a series of webinars, sharing data. They want to provide the pharmaceutical industry with data in order to avoid misconceptions, particularly about the manufacturing perspective.

Dr. Zenk stated that AmerisourceBergen wants the webinars to be just another vehicle to engage partners. She expects that probably by the third quarter of 2007, they will have data to give back to the industry and users. They are still in the phase of determining how data will move efficiently. They have solutions, and a pilot should be up and running by May 2007, which will be rolled out to end users in the third quarter of 2007. It's a step by step process, and they want to be sure it's compliant.

Mr. Powers asked if there were any questions for Dr. Zenk from the public. There were none.

Mr. Powers called on SupplyScape for their presentation.

Lucy Deus, Vice President of Product Development at SupplyScape, stated that she would share information about their interim drug pedigree messaging standard during the 2006 timeframe. She used that information as a basis for how things went, what they learned, and how things must be different to comply with California's requirements. She stated that they leverage pedigree data into their other business operations. A copy of her presentation is attached to this meeting summary.

She commented that there are substantial business opportunities for companies to gain a return on their investment in adopting pedigrees, and a major retail pharmacy participated in tracking and storing pedigree dates for one year. The memory storage requirements turned out to be quite small for 50 million items: it required

700 MB of storage, which on new computers 100 times this amount of memory is about $50.

Ms. Deus emphasized that all benefits of electronic pedigree are not automatic. Companies need to look to their business operations and recognize how data generated from electronic tracking can benefit their operations.

She added that there are about six vendors working on interoperability issues, plus some additional "home grown" solutions developed by individual entities. She stated that businesses need to integrate pedigree software into "critical touch" points in business practices, which will aid companies in gathering data in other business operations. For example, physical and financial information regarding inventory, returns reconciliation, shelf life management, and facilitated identification of lots subject to recalls. She stated that companies need to test systems internally to make certain they work, then coordinate details with trading partners.

President Powers emphasized that the board is a consumer protection agency. E-pedigree is the law in California and 2009 is the implementation date. The board encourages all stakeholders to participate in development of the standards, making certain their operational needs are considered.

d. Question and Answer Session and General Discussion

There were a few comments from attendees on different enforcement issues. Greg Light, from Omnicare stated that his company primarily serves patients in long-term care and residential care facilities. Regulations are strict on skilled nursing facilities, however, for those residents in assisted-living facilities, the pharmacy is being asked to handle returned medications from patients. He is concerned that there are no regulations in place regarding how pharmacies handle those returned medications. There are two or three possibilities each time for drug diversions to occur. Drugs are returned in grocery bags, coffee cans, some are labeled, some are not; some are outdated. It puts pharmacies in the position of being medical waste haulers, but their primary concern is diversion.

Mr. Light asked the board for further instructions on how to deal with this effectively. He saw that *The Script* addressed returning drugs for credit from assisted-living care.

Mr. Goldenberg asked if the board should put the issue of guidelines on a future agenda.

Mr. Powers said that there were some attempts in the past to deal with the issue legislatively. He stated that the matter will be placed on a future agenda.

Mr. Goldenberg clarified that skilled nursing facilities are regulated by the Department of Social Services. He said they should look at whether the board

should be meeting with the Department of Social Services or the Department of Health Services.

Ms. Herold stated that because of the diversion issue, the Enforcement Committee is the right committee for this issue. She said that the board should discuss possible resolutions. Under consideration in the California Legislature is a bill (Simitian) that would mandate pharmacies to take back returned medications.

Mr. Powers asked if there were any further questions or comments.

Drew Harrison, from Baxter Care, stated that he wanted to underscore business processes. He would like clarification from the board regarding granularity – how low does electronic tagging need to go. The law says pedigree must track from the smallest manufacturer's container level. For Baxter, the lowest level may be a shelf pack or case – the item is never broken down, shipped or sold in smaller units. He asked for guidance. Mr. Harrison stated that the consequences of tagging at the unit level, especially for some products, could defeat the intent of the law. Baxter requested the board's interpretation of law.

Mr. Room stated that the board wants to hear industry-level feedback as to whether tracking back to granularity would be a challenge. The law requires tracking down to an individual container, but if that provides challenges and if exceptions are needed by way of regulation, the board can provide that if we know that business processes are hampered by that. The board wants to know is being experienced by the industry.

Mr. Harrison asked if the board wants documentation as to the challenges created by unit dosages.

Mr. Room responded that yes, the board welcomes that feedback, and that Executive Officer Herold will accept that information.

Adjournment

There being no additional business, Chairperson Powers adjourned the meeting at 11:58 a.m.

Attachments for these meeting minutes (PowerPoint presentations by EPCglobal, AmerisourceBergen and Supply Scape) can be found in the Enforcement Committee segment of the April 18, 2007 Board of Pharmacy Meeting Materials. They are not reproduced here to conserve paper.

Attachment B

Enforcement Data
July 1, 2006 – March 31, 2007

Board of Pharmacy Enforcement Statistics
Fiscal Year 2006/2007

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 06/07
Complaints/Investigations					
Initiated	378	373	377		1128
Closed	412	266	553		1231
Pending (at the end of quarter)	671	922	815		815
Cases Assigned & Pending (by Team)					
Compliance Team	103	85	81		81
Drug Diversion/Fraud	106	125	118		118
Mediation Team	85	57	127		127
Probation/PRP	56	65	61		61
Enforcement	94	186	172		172
Application Investigations					
Initiated	68	97	75		240
Closed					
Approved	3	14	73		90
Denied	2	3	1		6
Total*	6	17	80		103
Pending (at the end of quarter)	98	178	174		174
Citation & Fine					
Issued	141	121	343		605
Citations Closed	172	124	120		416
Total Fines Collected	$75,815.00	$90,701.70	$131,910.00		$298,426.70

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2006/2007

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 06/07
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	35	20	44		99
Pleadings Filed	24	22	24		70
Pending					
Pre-accusation	59	52	46		46
Post Accusation	86	69	64		64
Total	149	128	143		143
Closed**	23	38	30		91
Revocation					
Pharmacist	1	4	6		11
Pharmacy	1	3	0		4
Other	9	14	12		35
Revocation,stayed; suspension/probation					
Pharmacist	1	2	1		4
Pharmacy	0	0	0		0
Other	0	0	1		1
Revocation,stayed; probation					
Pharmacist	1	1	4		6
Pharmacy	0	0	0		0
Other	0	0	1		1
Suspension, stayed; probation					
Pharmacist	0	0	0		0
Pharmacy	0	0	0		0
Other	0	0	0		0
Surrender/Voluntary Surrender					
Pharmacist	3	7	6		16
Pharmacy	0	5	0		5
Other	1	4	2		7
Public Reproval/Reprimand					
Pharmacist	0	0	0		0
Pharmacy	0	0	0		0
Other	0	0	1		1
Cost Recovery Requested	$40,239.00	$142,128.75	$53,344.75		$235,712.50
Cost Recovery Collected	$21,104.66	$39,650.49	$29,020.38		$89,775.53

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics
Fiscal Year 2006/2007

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 06/07
Probation Statistics					
Licenses on Probation					
Pharmacist	93	100	102		100
Pharmacy	5	6	6		6
Other	14	13	15		13
Probation Office Conferences	9	7	5		21
Probation Site Inspections	92	41	66		199
Probationers Referred to AG for non-compliance	3	0	0		3

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of 12/31/06)

Program Statistics					
In lieu of discipline	0	0	0		0
In addition to probation	2	4	2		8
Closed, successful	1	4	1		6
Closed, non-compliant	1	0	1		2
Closed, other	0	1	2		3
Total Board mandated Participants	50	54	53		54
Total Self-Referred Participants*	26	30	23		23
Treatment Contracts Reviewed	43	46	45		134

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, diversion program manager and supervising inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

As of March 31, 2007.

California State Board of Pharmacy
Citation and Fine Statistics
July 1, 2006 – March 14, 2007

561 citations have been issued so far this fiscal year

Total dollar amount of fines issued since July 1, 2006
$ 1,112,925.00

Total dollar amount of fines collected
$ 224,251.70*

*This amount also reflects payment of the citations issued before July 1, 2006.

The average number of days from date case is opened until a citation is issued is **120**

Average number of days from date citation is issued to date citation is closed is **45**

Citation Breakdown by license type

Total issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine	PIC no fine	TCH with fine	TCH no fine
561	94	14	138	68	80	23	16	2

Citation Breakdown by Miscellaneous license type

Wholesalers	Exemptee's	Clinics	Drug room	Exempt Hosp.	Hosp. pharmacy	Misc.	Unlicensed Premises	Unlicensed person
27	19	2	0	4	6	48	17	3

*Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

Top Ten Violations for the third quarter of 2006/2007 by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	45%	1716 - Variation from prescription	26%	1716 - Variation from prescription	9%
1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	9%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	14%	1715 – Self-assessment of a pharmacy by the pharmacist-in-charge	9%
4322 - Misdemeanor or infraction: false representation to secure license for self or others; false representation of licensure	4%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	7%	1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	9%
4339 - Non-pharmacist acting as manager, compounding, dispensing, or furnishing drugs	4%	4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	5%	4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	8%
4342 - Actions by board to prevent sales of preparations or drugs lacking quality or strength; Penalties for knowing or willful violation of regulations governing those sales	3%	1764/56.10et seq.- Unauthorized disclosure of prescription and medical information	4%	1716/1761(a) – Variation from prescription/No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	6%
1707.3 – Duty to review drug therapy	3%	1714(c)- Operational standards and security; the pharmacy must be maintained in a sanitary condition	3%	4063 - Refill of prescription for dangerous drug or device; prescriber authorization	5%
1714(d)- Operational standards and security; pharmacist responsible for pharmacy security	3%	1716/1761 - Variation from Rx / Erroneous Rx	3%	1714(b)- Operational standards and security; pharmacy responsible for pharmacy security	5%
4059(a)- Furnishing dangerous drugs without a prescription	3%	4063 - Refill of prescription for dangerous drug or device; prescriber authorization	2%	1304.11- Inventory requirements	4%
1764/56.10et seq.- Unauthorized disclosure of prescription and medical information	2%	4081(a)- Records of dangerous drugs kept open for inspection	2%	1707.2- Duty to consult	4%
4081(a)- Records of dangerous drugs kept open for inspection	2%	4115(e) - Pharmacy technician license required	2%	1711- Quality assurance programs	3%

Contested Citations Office Conference

(These statistics also include contested Letters of Admonishment)

There were thirteen office conferences held so far this fiscal year

Number of requests	170
Number appeared	104*

Number scheduled	170
Number Postponed	40**

*Please note on three occasions unscheduled citations were heard with a related case at office conference.
**Please note these are added back into the number of requests and scheduled case totals above.

Total number of requests withdrawn	26
Failed to appear	4

Office Conference results held between July 1, 2006 and February 22, 2007

Total number of citations affirmed	54

Decision	Total citations	Total dollar amount reduced
Modified	26	$9,725.00
Dismissed	18	$4,625.00
Reduced to Letter of Admonishment	1	$0.00

Please note due to additional investigation being required,
Three cases from SOC, are pending a decision

GOALS, OUTCOMES, OBJECTIVES, AND MEASURES

ENFORCEMENT COMMITTEE

Goal 1: Exercise oversight on all pharmacy activities.

Outcome: Improve consumer protection.

Objective 1.1: Achieve 100 percent closure on all cases within 6 months.

Measure: Percentage of cases closed.

Tasks:

1. Mediate all complaints within 90 days (for cases closed during quarter).

	N	< 90 days	< 120 days	< 180 days	Longer	Average Days
Qtr 1	141	113 (81%)	5 (3%)	11 (8%)	12 (8%)	50
Qtr 2	72	67 (94%)	0 (0%)	4 (5%)	1 (1%)	17
Qtr 3	113	100 (89%)	3 (3%)	4 (3%)	6 (5%)	32

2. Investigate all cases within 120 days (for cases closed during quarter).

	N	< 120 days	< 180 days	< 270 days	Longer	Average Days
Qtr 1	271	195 (72%)	49 (18%)	25 (9%)	2 (1%)	87
Qtr 2	173	146 (84%)	15 (9%)	12 (7%)	0 (0%)	79
Qtr 3	438	290 (66%)	107 (24%)	29 (7%)	12 (3%)	82

3. Close (e.g., no violation, issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.

Qtr 1	N	< 180	< 270	< 365	> 365
Closed, no additional action	210	166	14	15	15
Cite and/or fine letter of admonishment	167	82	50	25	10
Attorney General's Office	35	11	7	10	7
Qtr 2	**N**	**< 180**	**< 270**	**< 365**	**> 365**
Closed, no additional action	104	94	6	3	1
Cite and/or fine letter of admonishment	128	33	84	6	5
Attorney General's Office	12	2	4	3	3
Qtr 3	**N**	**< 180**	**< 270**	**< 365**	**> 365**
Closed, no additional action	172	157	12	3	0
Cite and/or fine letter of admonishment	631	337	16	7	1
Attorney General's Office	18	10	6	2	0

Objective 1.2	Manage enforcement activities for achievement of performance expectations.
Measure:	Percentage compliance with program requirements.
Tasks:	

1. Administer the Pharmacists Recovery Program.

	Voluntary Participants	Participants Mandated Into Program	Noncompliant, Terminated From Program	Successfully Completed Program
Qtr 1	26	50	1	1
Qtr 2	30	54	0	4
Qtr 3	23	53	1	1

2. Administer the Probation Monitoring Program.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Individuals	107	100	116	
Sites	5	6	7	
Tolled	27	27	20	
Inspections Conducted	92	41	66	
Successfully Completed	1	1	1	
Petitions to Revoke Filed	3	0	0	

3. Issue all citations and fines within 30 days.

	N	30 days	60 days	90 days	> 90 days	Average Days
Qtr 1	140	41 (29%)	61 (43%)	21 (15%)	17 (12%)	51
Qtr 2	118	14 (12%)	22 (18%)	41 (35%)	41 (35%)	84
Qtr 3	340	73 (21%)	77 (23%)	123 (36%)	67 (20%)	70

4. Issue letters of admonishment within 30 days.

	N	30 days	60 days	90 days	> 90 days	Average
Qtr 1	33	30 (91%)	1 (3%)	2 (6%)	0 (0%)	12
Qtr 2	4	4 (100%)	0 (0%)	0 (0%)	0 (0%)	18
Qtr 3	9	3 (33%)	0 (0%)	4 (44%)	2 (22%)	62

5. Obtain immediate public protection sanctions for egregious violations.

	Interim Suspension Orders	Automatic Suspension Based on Conviction	Penal Code 23 Restriction
Qtr 1	0	0	2
Qtr 2	0	0	1
Qtr 3	0	0	0

6. Submit petitions to revoke probation within 30 days for noncompliance with terms of probation.

	30 days	60 days	> 60 days	N
Qtr 1	1	0	2	3
Qtr 2	0	0	0	0
Qtr 3	0	0	0	0

Objective 1.3

Achieve 100 percent closure on all administrative cases within 1 year.

Measure:

Percentage of administrative cases closed within 1 year.

	N	1 Year	1.5 Year	2 Year	2.5 Year	>2.5 Years	Average
Qtr 1	22	6	11	3	1	1	456 days
		(27.3 %)	(50 %)	(13.6%)	(4.6%)	(4.6%)	
Qtr 2	37	13	11	7	2	4	568 days
		(35.1%)	(29.7%)	(18.9%)	(5.4%)	(10.8%)	
Qtr 3	29	16	7	2	2	2	444 days
		(55.2%)	(24.1%)	(6.9%)	(6.9%)	(6.9%)	

Objective 1.4	Inspect 100 percent of all facilities once every 3 year inspection cycle ending 6/30/08.
Measure:	Percentage of licensed facilities inspected once every 3 year cycle.
Tasks:	1. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public.

	Number of Inspections	Aggregate Inspections This Cycle	Percent Complete
Qtr 1	634	2,735	37%
Qtr 2	587	3,042	41%
Qtr 3	590	3,279	45%

2. Inspect sterile compounding pharmacies initially before licensure and annually before renewal.

	Number of Inspections	Number Inspected Late
Qtr 1	77	1
Qtr 2	50	1
Qtr 3	72	0

3. Initiate investigations based upon violations discovered during routine inspections.

	Number of Inspections	Number of Investigations Opened	Percent Opened
Qtr 1	634	33	5%
Qtr 2	587	25	4%
Qtr 3	590	20	3%

Objective 1.5	Initiate policy review of 25 emerging enforcement issues by June 30, 2011.
Measure:	The number of issues.
Tasks:	1.1. Monitor the implementation of e-pedigree on all prescription medications sold in California. *Sept. 28, 2006:* *Board convenes third Workgroup on Implementation of E-Pedigree Meeting. Presentations provided by EPCglobal, McKesson, Supervising Inspector Nurse and Johnson and Johnson.* *Sept. 30, 2006:* *Governor signs SB 1476 which delays implementation of e-pedigree requirements until 2009, requires serialization and interoperability and notification to the board whenever counterfeit drugs are discovered.* *Oct. 6, 2006:* *FDA provides presentation on federal pedigree requirements at board-hosted NABP District 7 & 8 Meeting.* *Dec. 2006:* *Board convenes fourth Workgroup on Implementation of E-Pedigree Meeting. Presentations made by EPCglobal, McKesson, AmerisourceBergen and Cardinal. Pilot testing e-pedigree systems underway at each of the three large wholesalers. Standards for electronic pedigree to be finalized by January 2007 by EPCglobal.* *Jan. 2007:* *EPCglobal finalizes electronic messaging standards for electronic pedigrees.* *Feb. 2007:* *EPCglobal convenes regional meeting with hospitals to discuss implementation issues of e-pedigree in these facilities. Hospitals are encouraged to join the board's Workgroup on Implementation of E-Pedigree Meetings.* *March 2007:* *Two Board members and executive staff meet with nine EPCglobal representatives to walk through EPCglobal's messaging standards and business scenarios. The standard complies with California's e-pedigree requirements although some questions remain about situation-specific criteria.* *Board convenes fifth Workgroup on Implementation of E-pedigree Meeting. Presentations are made by EPCglobal, AmerisourceBergen and SupplyScape.* 2. Implement federal restrictions on ephedrine, pseudoephedrine or phenylpropanolamine products. *Sept. 2006:* *Final phase-in of federal requirements takes effect on September 30. Board newsletter provides information for licensees.* *Oct. 2006:* *Board adds Consumer friendly materials regarding sales of these drugs to its Website.* 3. Monitor the efforts of the DEA and DHHS to implement electronic prescribing for controlled substances. *Sept. 2006:* *DEA releases proposed rule to allow prescribers to issue 90 days' worth of Schedule II prescriptions at one time.* *Oct. 2006:* *Board considers proposed rule.* *Nov. 2006:* *Board submits letter supporting change in DEA policy allowing prescribers to write multiple prescriptions for Schedule II drugs with "Do not fill before (date)" at one time, eliminating the need for patients to revisit prescribers merely to obtain prescriptions.*